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Sentry at the Gate: A History of the CDC's Regulation of Biological Agents

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Abstract: This paper charts the history of the CDC's role in the regulation of biological agents, from its origins in the early 1970s as a monitor of physical package security to its current position as a barrier between would-be terrorists and their weapons. First, the paper discusses CDC regulation between 1971 and 1996, an era characterized by a narrow CDC approach to oversight focused on the physical safety of packages moving in interstate commerce. Next, the paper analyzes the rapid expansion of the CDC's regulatory authority in the late 1990s to respond to the rising threat of bioterrorism, highlighting the challenges that emerged for an agency with little enforcement experience and possessing conflicting obligations towards the "industry" it regulated: the scientific community. Finally, the paper highlights several outstanding issues facing the CDC as it continues to enhance its regulatory mission.

I.

The Centers for Disease Control and Prevention ("CDC"), located in Atlanta, Georgia, is one of the world's foremost public health institutions. As the lead federal agency charged with protecting the health and safety of United States citizens, the CDC works to diminish the threat of communicable disease by developing and applying disease prevention strategies, promoting environmental health initiatives, and improving state and local public health programs.

Since 1971, the CDC has sought to advance this mission by regulating the interstate shipment of biological agents. Biological – or etiologic – agents, the naturally occurring and sometimes genetically engineered microorganisms that cause infectious disease, have long been a subject of academic research by scientists seeking to eradicate the most deadly human scourges. The development of vaccines throughout the nineteenth and twentieth centuries, and subsequent efforts to eradicate diseases such as smallpox and polio, were largely based on studies of agent properties and characteristics. Today, research laboratories across the country hold expansive inventories of hundreds of biological agents, including those organisms that cause diseases such as anthrax, plague, and Ebola. Microbiologists and other researchers use these agents as reference cultures to minimize the incidence of illness and death due to infectious disease, and more recently, to increase the nation's preparedness for acts of bioterrorism. Because an accidental or intentional agent release could have profound public health consequences, the CDC subjects laboratories and other entities possessing and transferring agents to extensive regulatory oversight. As several commenters have noted, the CDC's regulatory measures may be the only barrier between a terrorist and his or her potential weapon.

However, the CDC's regulatory role has not always been marked by aggressive agent oversight. In fact, until real fears of a bioterrorist strike emerged in the mid-1990s, the CDC's authority was narrowly limited to ensuring that the shipment of biological agents minimized any risk of agent release into the environment. As a result of this narrow focus, and its lack of regulatory experience outside of biological agent control, many contemporary critics have questioned the CDC's institutional competence as a regulatory body in an age of bioterrorism, particularly as national security interests arguably demand greater federal vigilance and a law enforcement focus. Moreover, as the CDC's regulatory role has expanded to respond to the new threat of bioterrorism, the agency has increasingly struggled to balance measures designed to improve public safety with the need to protect the free exchange of cultures by its public health partners for legitimate research purposes. Instead of enhancing domestic security, extreme measures to control agents – even to guard against bioterrorists – could harm the nation's health if scientists cannot obtain cultures for biodefense purposes or to conduct infectious disease research.

This paper charts the history of the CDC's role in the regulation of biological agents, from its origins in the early 1970s as a monitor of physical package security to its current position as a barrier between would-be terrorists and their weapons. First, the paper discusses CDC regulation between 1971 and 1996, an era characterized by a narrow CDC approach to oversight focused on the physical safety of packages moving in interstate commerce. Next, the paper analyzes the rapid expansion of the CDC's regulatory authority in the late 1990s to respond to the rising threat of bioterrorism, highlighting the challenges that emerged for an agency with little enforcement experience and possessing conflicting obligations towards the "industry" it regulated: the scientific community. Finally, the paper highlights several outstanding issues facing the CDC as it continues to enhance its regulatory mission.

While the thrust of this paper is historical analysis, the issues related to the CDC's regulation of biological agents implicate a number of policy debates, some of which are touched upon in this discussion. For example, as agent regulation shifts even further from a public health to a law enforcement problem, questions are undoubtedly raised about whether the CDC is the proper institutional body in which to vest regulatory authority. Similarly, because of the importance of biological agents to a number of legitimate research goals – namely, disease eradication and the development of appropriate biodefense measures – real concerns remain about whether the CDC, at Congress' mandate, has entered an age of dangerous overregulation. While resolution of those policy issues will clearly be important as the CDC gains more experience and

effectiveness in agent regulation, those questions are not the the main focus of this paper, and thus are not given the level of attention or detail they deserve. The aim of this paper is far more modest: to explain how the CDC – traditionally an agency with no regulatory power – received its current role in the oversight of biological agents, and to demonstrate the challenges that have accompanied the CDC as its mandate has expanded in response to the current threat of bioterrorism.

II.

The CDC was established in 1942 as a component of the U.S. Public Health Service.¹ Initially named the “Malaria Control in War Areas” unit, the institution’s goal was relatively narrow: to combat malaria outbreaks, which at the time were threatening the success of the U.S. war effort.² However, in 1946, the unit was renamed the “Communicable Disease Center,” and broadened its mission appropriately.³ In the decades immediately following World War II, CDC efforts grew to include research on diseases of zoological origin and eventually surveillance of all health epidemics within the domestic United States.⁴ With the advent of President Lyndon Johnson’s “Great Society” in the early 1960s, the CDC’s role expanded even further to encompass public health programs as diverse as family planning, lead-based paint poisoning, and international disease eradication.⁵ In 1970, the CDC changed its name for the last time, to the familiar “Centers for Disease Control.”⁶ In 1973, it was officially elevated to agency status.⁷ Today, the CDC employs over 8,500 individuals in 170 disciplines and plays a critical part in protecting the nation from the “most widespread, deadly, and mysterious threats” against human health.⁸

The regulation of etiologic materials was not one of the CDC’s primary duties until August 3, 1971, when the Department of Health Services and Mental Health Administration (“DHSMHA”), a subdivision of the Department of Health, Education, and Welfare (“DHEW”), officially delegated to the CDC its authority to regulate the interstate shipment of etiologic agents and vectors.⁹ As a result of this delegation, the CDC

¹ELIZABETH ETHERIDGE, SENTINEL FOR HEALTH: A HISTORY OF THE CENTERS FOR DISEASE CONTROL xv (University of California Press 1992).

²*Id.*

³*Id.* at xv-xvi.

⁴*Id.* at xvi.

⁵*Id.* at xvii.

⁶*Id.*

⁷*Id.*

⁸See “About CDC,” www.cdc.gov.

⁹Statement of Organization, Functions, and Delegations of Authority, 36 Fed. Reg. 14280 (August 3, 1971). Under 42 U.S.C. § 264, DHEW, predecessor to the contemporary Department of Health and Human Services (hereinafter, “DHHS”), was

received its first – and, to date, only – regulatory mission, and assumed control of the official shipping, packaging, and labeling requirements delineated at 42 C.F.R. § 72.25.¹⁰

Including CDC in the regulation of the packaging and shipping of agents was intended to fill a critical gap in federal oversight of potentially infectious materials moving in interstate commerce: protection of the public health. Prior to the DHSMHA’s delegation, several federal agencies were already involved in regulating the packaging, labeling, and shipment of infectious materials within the United States. The Department of Transportation’s Hazardous Materials regulations, 49 CFR 171-180, governed the interstate transport by surface or air of infectious substances, medical waste, and chemical and radioactive materials.¹¹ Similarly, the United States Postal Service regulated the shipment of etiologic agents, clinical specimens, and other biological products through the mail, 39 CFR 111.¹² The Occupational Safety and Health Administration, a division of the Department of Labor, monitored worker safety during the handling, packaging, and transport of human blood, bodily fluids, unfixed tissues, and organs and cell cultures, 29 CFR 1910.¹³ Lastly, the Department of Commerce maintained a list of restricted items, including microorganisms, that could not be exported from the United States, 15 CFR 768-799.¹⁴ While these agencies brought important expertise

authorized to promulgate regulations to prevent the introduction, transmission, and spread of communicable disease. *See* 42 U.S.C. §264; *see also* Packaging and Handling of Infectious Substances and Select Agents, 64 Fed. Reg. 58022 (proposed Oct. 28, 1999) (to be codified at 42 C.F.R. pt. 72), for a brief discussion of the delegation. DHEW initially delegated supervisory authority over the interstate transportation of etiologic agents to DHSMHA on May 14, 1971. Redelelegation by the Assistant Secretary for Health and Scientific Affairs, 36 Fed. Reg. 8893 (May 14, 1971). Three months later, DHSMHA redelegated this regulatory authority to the CDC. *See infra*. The delegation was not mandated by statute but was rather an internal delegation conducted for reorganization purposes. E-mail from Arathi Almli, Attorney Advisor, Department of Health and Human Services, Office of the General Counsel, to Catherine Manzi, Student, Harvard Law School (Feb. 26, 2004, 16:29:22 EST) (on file with author).

¹⁰At the time the CDC received regulatory authority, the shipping and packaging requirements were found at 42 C.F.R. pt. 72.25, entitled “Etiologic Agents.” *See, e.g.*, Etiologic Agents, 36 Fed. Reg. 8815 (May 13, 1971) (to be codified at 42 C.F.R. pt. 72). When the CDC revised this rule on July 21, 1980, it renumbered the rule’s provisions and officially changed the title of 42 CFR pt. 72 from “Etiologic Agents” to “Interstate Shipment of Etiologic Agents.” Interstate Shipment of Etiologic Agents, 45 Fed. Reg. 48626 (July 21, 1980) (to be codified at 42 C.F.R. pt. 72). The renumbered sections were found at 42 C.F.R. §§ 72.1-72.5. *Id.*

¹¹Department of Transportation, Hazardous Materials Regulations, 49 C.F.R. Subtitle C, §§ 171-180 (2004). *See also* Packaging and Handling of Infectious Substances and Select Agents, 64 Fed. Reg. 58022, *supra* note 9, at 58023 for a discussion of overlapping federal regulations in the area of biological agent control.

¹²United States Postal Service, General Information on Postal Service, 39 C.F.R. § 111 (2004). *See also* Packaging and Handling of Infectious Substances and Select Agents, 64 Fed. Reg. 58022, *supra* note 9 at 58023.

¹³Occupational Safety and Health Administration, Toxic and Hazardous Substances, 29 C.F.R. §1910.1030 (2004). *See also* Packaging and Handling of Infectious Substances and Select Agents, 64 Fed. Reg. 58022, *supra* note 9, at 58023.

¹⁴Commerce and Trade, Foreign Availability Determination Procedures and Criteria, 15 C.F.R. §§ 768-799 (2004). *See also* Packaging and Handling of Infectious Substances and Select Agents, 64 Fed. Reg. 58022, *supra* note 9, at 58023. Several international organizations were also involved in monitoring the transport and shipment of biological agents. First, the United Nations Committee of Experts on the Transport of Dangerous Goods made recommendations on the international transport of infectious substances and clinical specimens, which were themselves included in the International Civil Aeronautics Organization technical instructions. *Id.* Second, the International Air Transport Association published the Dangerous Goods Regulations, which described for member airlines the U.N. recommendations for the air transport of biological materials, as well as relevant national guidelines. *Id.*

to bear on the issue of safety in agent transportation, they did not possess the institutional competence of the CDC in infectious disease control, and their regulations did not address public health concerns. More specifically, involving the CDC in packaging and shipment regulation allowed for an effective federal response to health concerns that arise due to damage to packages carrying deadly pathogens.¹⁵

The agent shipping and packaging requirements, 42 C.F.R. § 72.25, initially promulgated by the Surgeon General with the approval of DHEW, were designed to protect the public health by minimizing any potential for (1) direct physical contact with packages containing highly dangerous biological material, (2) contamination of the physical environment, and (3) spread of disease into the community.¹⁶ At the time of the DHSMHA delegation to the CDC, the regulation – in the process of amendment – included five fundamental components. First, the regulation established an official definition of “etiologic agent,” and specified 31 diseases covered by the definition and thus subject to the rule.¹⁷ According to the regulation, no etiologic agent could knowingly be transported in interstate commerce without meeting packaging standards.¹⁸ Second, the regulation provided specific guidance on the appropriate packaging and labeling of biological materials for transport, including the physical requirements for agent containers, the proper use of dry ice, the maximum volume of agent allowed per shipment, and the shipping documents to be effected for a legal transfer.¹⁹ Third, the regulation instituted measures to be taken in the event of damage during transport.²⁰ Fourth, the regulation mandated isolation of all affected areas following an agent release, pending clearance by the Surgeon General.²¹ Finally, the regulation specified procedures for notifying authorities if an agent package was not received.²²

For the first twenty-five years of its regulatory mandate, the CDC did not take an aggressive approach to regulation. In fact, the CDC instituted only two revisions to the DHEW’s initial rule between 1971 and

¹⁵Packaging and Handling of Infectious Substances and Select Agents, 64 Fed. Reg. 58022, *supra* note 9, at 58023.

¹⁶*Id.* at 58024. The Surgeon General first proposed inserting § 72.25 to govern the shipment of etiologic agents on December 18, 1956. *See* Interstate Quarantine, Shipment of Etiologic Agents, 21 Fed. Reg. 10015 (Dec. 18, 1956) (to be codified at 42 C.F.R. pt. 72). The Surgeon General issued a final rule codifying § 72.25 a year later. *See* Shipment of Etiologic Agents, 22 Fed. Reg. 954 (Feb. 1957) (to be codified at 42 C.F.R. pt. 72).

¹⁷*See* Shipment of Etiologic Agents, 22 Fed. Reg. 954 (Feb. 1957) (to be codified at 42 C.F.R. pt. 72). “Etiologic agent” was defined as the causative agent of a specific list of diseases regulated under the rule and listed by name in § 72.25(a), as well as “such others as may be prescribed from time to time by the Surgeon General.” *Id.* at §72.25(a).

¹⁸*Id.* The restrictions on transportation were codified at 42 C.F.R. § 72.25(b).

¹⁹*Id.* The packaging requirements were codified at 42 C.F.R. § 72.25(b)(1)-(5).

²⁰*Id.* The provisions concerning lost or damaged packages were codified at 42 C.F.R. § 72.25(c)(1)-(7).

²¹*Id.* The isolation mandate was codified at 42 C.F.R. § 72.25(d).

²²*Id.* The notification provision was codified at 42 C.F.R. § 72.25(e).

1996, both aimed at ensuring better physical protection of transported materials. First, following a notice of proposed rulemaking issued by DHEW on May 13, 1971, the CDC implemented an amended rule on June 30, 1972.²³ The amended rule revised the definition of “etiologic agent” to correspond to specific categories of causative agents (bacteria, viruses) rather than individually-named infectious diseases, added a definition of “diagnostic specimen” to the regulation, and detailed a list of nearly 90 bacterial, fungal, viral, and rickettsial agents to be affected by the packaging and shipment requirements.²⁴ It extended minimum packaging requirements to biological products, mandated shipment via registered mail for 11 highly infectious agents, replaced U.S. liquid measurements with metric measurements, tightened container requirements, and redesigned the DHEW-imposed hazardous materials warning label to mirror Department of Transportation identification standards.²⁵ Second, following publication of a notice of proposed rulemaking on November 21, 1979, indicating its intention to “expand and clarify” packaging, labeling, and shipping requirements for biological cultures and products and update the list of infectious agents covered by the rule, the CDC issued another amended rule on July 21, 1980.²⁶ The 1980 rule transferred the provisions relating to interstate quarantine to the Food and Drug Administration and changed the title of the regulation from “Etiologic Agents” to “Interstate Shipment of Etiologic Agents.”²⁷ More importantly, the new rule included a definition of “interstate traffic,” added several agents to the list of monitored bacteria, viruses, fungi, and rickettsia, and clarified restrictions on shipping containers and warning labels.²⁸ Finally, the 1980 amendment renumbered the rule’s subparts for greater ease of administration.²⁹

The CDC’s 1980 rule remained unamended until 1996. Because the CDC rule was intended solely to prevent

²³Etiologic Agents, 37 Fed. Reg. 12915 (June 30, 1972) (to be codified at 42 C.F.R. pt. 72).

²⁴*Id.* Notably, for the purposes of the amended rule, “etiologic agent” was defined as “a viable microorganism or its toxin which causes human disease.” *Id.* “Diagnostic specimen” was defined to mean “any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue, and tissue fluids.” *Id.* These definitions were codified at 42 C.F.R. § 72.25(a). *Id.* The agent list was codified at 42 C.F.R. § 72.25(c).

²⁵*Id.* The restrictions on packaging and labeling were codified at 42 C.F.R. § 72.25(d)-(h).

²⁶Interstate Shipment of Etiologic Agents, 45 Fed. Reg. 48626, *supra* note 10. After publishing its notice of proposed rulemaking in November 1979, the CDC invited written comments, to be received before January 21, 1980. By the time the comment period expired, the CDC had received written and telephone comments from “a limited number” of interested parties. The comments in large part concerned notice requirements in the event of delayed receipt of an agent shipment, overlap between the CDC hazard warning label and other labeling requirements imposed by the International Air Transport Association (“IATA”), expansion of the etiologic agent list to include specific biological materials, confusion over nomenclature, and the maximum volume of agent allowed per package. Few of the comments were incorporated into the final rule. *See id.*

²⁷*See id.* at 48627.

²⁸*See id.* at 48628-9. To give just one example of the clarifications instituted by the new rule, “nonparticulate absorbent material,” required when shipping agents in aggregate volumes of less than 50 ml, was noted to include “paper towels.” *Id.*

²⁹*See infra* note 2. The new subsections were: § 72.1, Definitions; § 72.2, Transportation of Diagnostic Specimens, Biological Products, and Other Materials, Minimum Packaging Requirements; § 72.3, Transportation of Materials Containing Certain Etiologic Agents, Minimum Packaging Requirements; § 72.4, Notice of Delivery, Failure to Receive; and § 72.5 Requirements; Variations.

unsafe distribution of hazardous materials by legitimate research facilities, it did not impose restrictions on agent acquisition or possession. In fact, under the pre-1996 regulatory regime, any individual could legally procure an etiologic agent, subject only to self-imposed – and often minimal – seller restrictions. CDC oversight was only relevant to post-acquisition shipment across state lines.³⁰ Consequently, the CDC regime did little to prevent misappropriation or misuse of etiologic agents.³¹ As one commentator noted, the regulation was developed for “narrow purposes in an era when most lawmakers did not consider domestic bioterrorism as a realistic possibility.”³² It was not until the passage of the Antiterrorism and Effective Death Penalty Act of 1996 (“AEDPA”) that the CDC’s regulatory role shifted to respond to the rising threat of bioterrorism.

III.

The first major expansion of the CDC’s regulatory authority to account for new dangers related to the threat of bioterrorism occurred in reaction to two high-profile incidents involving the illicit acquisition of poisonous material. In mid-March 1995, the Japanese cult Aum Shinrikyo released nerve gas in an unprecedented attack on the Tokyo subway, killing 12 and injuring another 5,000.³³ Although Aum’s weapon of choice – sarin – was of chemical origin, an investigation into the attack revealed a disconcerting 10-year quest by the cult to develop lethal biological weapons.³⁴ Notably, the cult had purchased a 48,000-acre range in Australia for use as a “biological weapons laboratory,” sent members to Zaire in an attempt to obtain samples of the highly lethal Ebola virus, and undertook at least four separate – though ultimately unsuccessful – bioterrorist strikes in Japan before the March attack.³⁵ Arrested cult members admitted plans to attack both New York

³⁰See 142 CONG. REC. S1856 (daily ed. March 12, 1996) (statement of Sen. Hatch, Chairman, Senate Comm. on the Judiciary), at S1862; see also *Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of Barth Reller, Member of the Board for the American Type Culture Collection and Director of Clinical Microbiology, Duke University Medical Center).

³¹See Barry Kellman, *Biological Terrorism: Legal Measures for Preventing Catastrophe*, 24 HARV. J.L. & PUB. POL’Y 417, 448 (2001).

³²Heather A. Dagen, *Bioterrorism: Perfectly Legal*, 49 CATH. U. L. REV. 535, 555 (2000).

³³James H. Anderson, *Microbes and Mass Casualties: Defending America Against Bioterrorism*, Heritage Foundation Reports No. 1182, May 26, 1998, p. 4; see also Leonard A. Cole, *The Specter of Biological Weapons*, SCI. AM., Dec. 1996, available at <http://www.sciam.com/1296issue/1296cole.html>.

³⁴*Id.*

³⁵*Id.* at 5.

and Washington, D.C. with purified biological material.³⁶ On May 5, less than six weeks after the Aum's Tokyo subway release, Larry Wayne Harris, a trained microbiologist and lieutenant in the neo-nazi group Aryan Nations, succeeded in ordering three vials of yersinia pestis, the biological agent that causes bubonic plague, from the American Type Culture Collection ("ATCC") in Rockville, MD.³⁷ To obtain the cultures, Harris had provided the ATCC with a copy of his membership certificate from the American Society for Microbiologists and a letter indicating that he owned the Small Animal Microbiology Laboratory, a non-existent research facility allegedly certified and approved by the Ohio Environmental Protection Agency.³⁸ Despite the fact that plague is treatable with standard antibiotics, Harris told the ATCC that he needed the agent for research designed to "counteract Iraqi rats carrying 'supergerms.'" ³⁹ His actions were deemed suspicious only when he contacted the ATCC four days after his request to determine why the cultures had not yet arrived.⁴⁰ Harris eventually pled guilty to mail fraud and was sentenced to eighteen months probation by a federal court.⁴¹ As one observer noted, to obtain the plague bacteria, Harris needed "no more than a credit card and a false letterhead."⁴²

Both the Harris and Aum incidents sent a warning signal to policymakers and the public regarding the ease with which terrorists and other uncertified individuals could access deadly pathogens. The Department of Health and Human Services ("DHHS"), the federal agency responsible for the state of domestic health, responded quickly to what was portrayed as a classic failure in oversight. In early June, the Department directed the CDC to chair, along with the DHHS Office of Emergency Preparedness ("OEP"), an informal, interdepartmental working group charged with reviewing existing agent controls.⁴³ The working group, composed primarily of federal scientists and health professionals, met throughout the summer of 1995 to examine the safeguards in place for the sale of Biosafety Level 3 and Biosafety Level 4 organisms and recombinant DNA products, and to analyze the adequacy of the laws and regulations governing the acquisition

³⁶*Id.*

³⁷Jill Riepenhoff & Jim Woods, *Plague Vials Found in Car; Lancaster Man Charged, Got Cultures Through the Mail*, COLUMBUS DISPATCH, May 13, 1995, at 1A; Kellman, *Biological Terrorism: Legal Measures for Preventing Catastrophe*, *supra* note 31, at 449. Professional societies of scientists established the American Type Culture Collection in 1925 as a clearinghouse for pure strains of microorganisms. Its stock numbers 82,000 frozen cultures. See Karl Vick, *Man Gets Hands on Bubonic Plague Germ, but That's No Crime*, WASH. POST, Dec. 30, 1995, at D1.

³⁸Riepenhoff & Woods, *supra* note 37, at 1A.

³⁹Kellman, *Biological Terrorism: Legal Measures for Preventing Catastrophe*, *supra* note 31, at 449; see also Cole, *supra* note 33, available at <http://www.sciam.com/1296issue/1296cole.html>.

⁴⁰Cole, *supra* note 33, available at <http://www.sciam.com/1296issue/1296cole.html>.

⁴¹Robert Ruth, *Harris Pleads Guilty, Is Free*, COLUMBUS DISPATCH, March 25, 1998, at A1.

⁴²Cole, *supra* note 33, available at <http://www.sciam.com/1296issue/1296cole.html>.

⁴³*Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control).

and shipment of etiologic agents.⁴⁴ On the working group's recommendation, Dr. Philip Lee, the DHHS Assistant Secretary for Health, formed a second committee in August composed of representatives from the CDC, the Food and Drug Administration, and the National Institutes of Health to further study the issue.⁴⁵ The second committee – again co-chaired by the CDC and OEP – also included officials from the Environmental Protection Agency, U.S. Postal Service, and U.S. Departments of Commerce, Justice, and Transportation, who actively participated in the committee deliberations.⁴⁶ The purpose of the committee, which was broader than its informal predecessor, was to (1) integrate across federal departments, to the greatest extent possible, existing regulations governing the shipment of infectious agents in interstate commerce, (2) prepare a list of agents to be monitored, (3) prepare a new legal framework for the enforcement of agent controls, and (4) consider suitable criminal penalties to complement any regulatory oversight.⁴⁷ The committee was also charged with evaluating the necessity of a central registry for tracking the purchase of restricted recombinant DNA materials.⁴⁸ Over the course of the next year, the committee would propose a significant enhancement of the CDC's regulatory role.

⁴⁴*Id.* Four official Biosafety Levels are outlined in the DHHS manual *Biosafety in Microbiological and Biomedical Laboratories*. See *id.* The most current version of the manual was published in 1999. CENTERS FOR DISEASE CONTROL AND PREVENTION & NATIONAL INSTITUTES OF HEALTH, BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES, FOURTH EDITION (1999) (hereinafter, “BMBL”). The highest Biosafety Level, 4, pertains to agents that must be worked on under maximum containment laboratory conditions. See *Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control), *supra* note 43; see also BMBL at 13-14. There are currently two Biosafety Level 4 facilities in the U.S.: one at CDC headquarters in Atlanta and the other at Fort Dietrick, MD. See *Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control), *supra* note 43. Biosafety Level 3 pertains to agents that are dangerous in the laboratory setting due to their facile transmission via needle stick or inhalation, but which are not as dangerous or infectious as Biosafety Level 4 agents. See *id.*; see also BMBL, at 13. In general, for agents classified at Biosafety Level 3, effective treatments or vaccines are not available. See *Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control), *supra* note 43. Biosafety Level 2 is the level on which most work is done in clinical microbiology laboratories. A Biosafety Level 2 certification allows a laboratory to work with the vast majority of infectious agents that cause disease but that do not pose great risk to laboratory workers. See *id.*; see also BMBL, at 12-13. Finally, Biosafety Level 1 involves work done on microorganisms that are not known to cause human disease. See *Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control), *supra* note 43; see also BMBL, at 11-12.

⁴⁵*Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control), *supra* note 43.

⁴⁶See *id.*; see also *Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of Mark M. Richard, Deputy Assistant Attorney General, Criminal Division, Department of Justice).

⁴⁷*Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control), *supra* note 43.

⁴⁸See *id.*

Eight months into the interagency committee's tenure, the Senate Judiciary Committee held hearings on the interstate transport of human pathogens, and invited group members to testify as to their findings. In proceedings attended by members of the House of Representatives as well as officials from the Department of Justice, the CDC, and the scientific community, the committee revealed significant gaps in the regulation of etiologic agents.⁴⁹ Specifically, committee members testified that despite the existence of overlapping federal regulations instituted by the CDC, the Department of Transportation, and the Department of Commerce, among others, governing the shipment of etiologic materials, no comprehensive legal framework existed to control access to dangerous pathogens.⁵⁰ In fact, as Senator Hatch noted, the only restrictions on access to etiologic agents in 1995 were "imposed by the sellers of the pathogens themselves."⁵¹ It was simply not illegal for any individual to order a pathogen culture; instead, the system relied on private suppliers to make "judgment calls" in accordance with internal laboratory policy.⁵² Mark Richard, the Deputy Assistant Attorney General for the Criminal Division, U.S. Department of Justice, underlined that additional legislation was needed to "tighten up the overall system" and to fully develop and implement a comprehensive regulatory scheme.⁵³ Congressman Markey concurred, emphasizing that he believed "quite firmly that we should just pass a law to ensure that, permanently, there will be a control regime" placed over etiologic materials.⁵⁴

At the time of the hearings, the CDC-chaired interagency committee had already developed preliminary re-

⁴⁹*Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996). The witness list included Rep. John R. Kasich (R-OH, 12th); Rep. Edward J. Markey (D-MA, 7th); Rep. Joseph P. Kennedy II (D-MA, 8th); Mark Richard, Deputy Assistant Attorney General, Criminal Division, Department of Justice; James Hughes, Assistant Surgeon General and Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention; David N. Sundwall, President, American Clinical Laboratory Association; Kenneth Berns, President, American Society of Microbiology, and Chairman, Department of Microbiology, Cornell University Medical College; and Barth Reller, Member of the Board for the American Type Culture Collection and Director of Clinical Microbiology, Duke University Medical Center.

⁵⁰*Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of Mark M. Richard, Deputy Assistant Attorney General, Criminal Division, Department of Justice), *supra* note 46.

⁵¹*See* 142 CONG. REC. S1856 (daily ed. March 12, 1996) (statement of Sen. Hatch), *supra* note 30, at S1862. In introducing the Biological Agents Enhanced Penalties and Controls Act, Senator Hatch noted that in 1996, biological agents were generally available for three legitimate purposes. *See id.* First, small quantities of agents could be found in patient samples analyzed for diagnostic purposes at clinical laboratories. *See id.* Second, scientists and medical professionals conducting legitimate clinical research projects often used biological agents. *See id.* Third, the Department of Defense possessed a number of biological agents used in developing protective strategies in the event of a wartime release. *See id.*

⁵²*Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of Mark M. Richard, Deputy Assistant Attorney General, Criminal Division, Department of Justice) (responding to questions posed by Sen. Feinstein); *see also Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (testimony of David N. Sundwall, President, American Clinical Laboratory Association, in response to questions posed by Sen. Hatch) (discussing principles of conduct that apply in laboratories handling biological agents).

⁵³*Id.*

⁵⁴*Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of Rep. Markey).

visions to the CDC regulations governing the interstate shipment of etiologic materials, in close conjunction with the scientific research community.⁵⁵ The revisions allowed for collection of information concerning the location of etiologic agents across the United States, as well as for certification and tracking of agent transfers between laboratories and other individuals.⁵⁶ The revisions also established a process for alerting law enforcement and appropriate federal authorities in the event of an unauthorized attempt to acquire a deadly pathogen.⁵⁷ According to the CDC, the revisions were consistent with the agency's pre-existing authority and could be formally prepared in as little as 180 days, although committee members admitted that further modifications were necessary to finalize a list of restricted agents and to ensure that "appropriate protections such as accountability, orderability, and adequate federal oversight of the program are included."⁵⁸ Nevertheless, while clearly supporting the interagency – and Congressional – call for greater agent controls, the CDC appeared considerably more reticent about instituting a formal legal regime, primarily because of fears that strict laws would obstruct legitimate and beneficial scientific research. As James Hughes, Assistant Surgeon General and Director of the National Center for Infectious Diseases at the CDC, stated, a formal system would likely lead to the "inhibition of really high priority ongoing scientific research."⁵⁹ His view was echoed by the three panelists representing scientific interests before the Judiciary Committee.⁶⁰ In the words of one panelist, any program to respond to the danger of unauthorized access to etiologic agents "should be carefully weighed and... balanced to avoid over-regulation and intrusive schemes that could interfere with the flow of research activities in academia and industry."⁶¹ Panelists from the scientific community also emphasized that placing responsibility at the insitutional level would not only allow for appropriate moni-

⁵⁵*Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control), *supra* note 43.

⁵⁶*See id.*

⁵⁷*See id.*

⁵⁸*See id.*; *see also Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of Mark M. Richard, Deputy Assistant Attorney General, Criminal Division, Department of Justice) (responding to questions posed by Sen. Hatch). Regarding CDC's authority to regulate biological agents, *see* 142 CONG. REC. S1856 (daily ed. March 12, 1996) (statement of Sen. Hatch, Chairman, Senate Comm. on the Judiciary), at S1863 (noting that "the CDC has wide authority to regulate biological agents that pose a threat to human health, and could establish rules limiting who may possess these agents").

⁵⁹*Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control) (responding to questions posed by Sen. Feinstein).

⁶⁰Those three panelists were: David N. Sundwall, President, American Clinical Laboratory Association; Kenneth Berns, President, American Society of Microbiology, and Chairman, Department of Microbiology, Cornell University Medical College; and Barth Reller, Member of the Board for the American Type Culture Collection and Director of Clinical Microbiology, Duke University Medical Center. *See Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996).

⁶¹*Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of Kenneth Berns, President, American Society of Microbiology, and Chairman, Department of Microbiology, Cornell University Medical College).

toring but would also be “the least inhibitory to research.”⁶² The scientific community’s fears of suffocating government regulation proved to be a harbinger of future debates surrounding the appropriate role of the CDC and other federal agencies in the monitoring of agents. Despite their highly vocal insistence on stricter agent controls, Chairman Hatch and other Judiciary Committee members softened their demands for the most stringent measures in response to the objections.

The Senate Judiciary Committee’s reaction to the interagency testimony was swift. Chairman Orrin Hatch, expressing concern that 180 days was an unacceptably long time to wait for the institution of a regulatory scheme given the potentially catastrophic results of unauthorized access, urged his colleagues to insert additional language into the Antiterrorism Bill currently before the Senate.⁶³ On March 12, 1996, only six days after the close of the hearings, Hatch introduced S.1606, the Biological Agents Enhanced Penalties and Control Act (“Biological Agents Act”), a bill eventually incorporated into the AEDPA.⁶⁴ In introducing the

⁶²See *id.* Dr. Reller also stated that “we need to find an appropriate balance in the inherent dynamic tension between society’s need to avoid misappropriation of biologicals for nefarious purposes and society’s interest in assuring minimally encumbered availability and transferability of biologicals within the scientific and industrial communities.” *Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of Barth Reller, Member of the Board for the American Type Culture Collection and Director of Clinical Microbiology, Duke University Medical Center), *supra* note 30.

⁶³Prior to the Senate hearings, Reps. John R. Kasich (R-OH, 12th), Edward J. Markey (D-MA, 7th), and Joseph P. Kennedy II (D-MA, 8th) had introduced legislation in the House, the “Biological Weapons Restrictions Act of 1996,” to add provisions criminalizing the misuse of biological organisms to existing laws related to weapons of mass destruction. See *Interstate Transportation of Human Pathogens: Hearing Before the Senate Comm. on the Judiciary*, 104th Cong. (1996) (statement of Rep. Kennedy) (further noting that the FBI, CDC, and Department of Justice had unanimously recommended these provisions). The Kasich-Markey-Kennedy legislation was successfully attached to the AEDPA and passed the House by a vote of 229-191. See John M. Biers, *House Votes to Punish Virus Terrorism*, STS. NEWS Service, March 14, 1996. Rep. Markey further introduced a bill requiring increased CDC oversight of dangerous pathogens, although his bill was eventually excluded from the AEDPA for procedural reasons. See *id.* The Senate placed considerable pressure on the Clinton administration to respond to the Harris incident through executive action. Following the Senate hearings, Senator Hatch, along with Senators Feinstein, Specter, and Kohl, sent a letter to President Clinton urging that he direct the CDC to implement emergency procedures against the threat of stolen pathogens on a priority basis. See 142 CONG. REC. S1856 (daily ed. March 12, 1996) (statement of Sen. Hatch, Chairman, Senate Comm. on the Judiciary), *supra* note 30, at S1863. The Congressional pressure appeared to have some effect: on March 11, 1996, the day before the Senate introduced legislation imposing new restrictions on the transfer of biological agents, CDC Director David Satcher dispatched a letter to laboratories known to be handling highly dangerous pathogens requesting increased vigilance in their acquisition and transfer in order to minimize the risk of illicit access. See Letter from David Satcher, Director, Centers for Disease Control and Prevention, March 11, 1996, FDCH Federal Department and Agency Documents. Satcher defined “increased vigilance” to include reviewing all agent requests prior to transfer, determining whether requested agents would be used for legitimate medical or scientific purposes, and reporting any suspicious inquiries or transactions. See *id.* The Satcher letter also informed laboratories that the CDC would be proposing new regulations regarding the acquisition and transfer of certain agents, with appropriate input from professional associations, the research community, the public, and law enforcement. See *id.*

⁶⁴See Dagan, *supra* note 32, at 553; see also Bill Summary & Status File for S. 1606, THOMAS: Legislative Information on the Internet (hereinafter, “THOMAS”), a Library of Congress website, available at thomas.loc.gov, last visited on April 5, 2004. The Biological Agents Act was co-sponsored by Senators Feinstein, Thurmond, Dewine, Kohl, and Biden. See *id.*; see also 142 CONG. REC. S1856 (daily ed. March 12, 1996) (statement of Sen. Hatch, Chairman, Senate Comm. on the Judiciary),

Biological Agents Act, Hatch criticized the existing CDC packaging and shipping regulation for failing to guard against illicit agent possession and use, failing to reflect scientific advances in the fifteen years since its last revision, and failing to avoid substantive overlap with other federal regulations governing the shipment of biological material.⁶⁵ The new legislation thus mandated that the CDC regulate the registration and transfer of agents of “unique interest,” and officially charged the CDC with “preventing access to dangerous biological agents for use in domestic and international terrorism or for any other purpose.”⁶⁶ The Act defined “biological agent” pursuant to 18 U.S.C. § 178, the criminal statute governing the illicit use of biological weapons. This definition proved somewhat broader than the CDC’s earlier definition of “etiologic agent,” encompassing “any microorganism...or infectious substance...capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism,” as well as substances “[capable of causing] deterioration of food, water, equipment, supplies, or material of any kind” or “[capable of causing] deleterious alteration of the environment.”⁶⁷ While seeking to balance the needs of the scientific community to use and access agents without overly-burdensome oversight and the needs of the public to be protected from potential bioterrorists, the Biological Agents Act instituted two significant changes to the

supra note 30, at S1862. Reps. Kasich, Kennedy, and Markey authored the House version. *See The Threat of Bioterrorism in America, Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. 36-37 (1999).

⁶⁵Senator Hatch specifically criticized the CDC’s lack of momentum in his statements introducing the Biological Agents Enhanced Penalties and Control Act. As Hatch stated: “unfortunately, efforts by CDC and others have been slow. To date, there have been at least two multiagency task forces established to look at this issue. The first task force completed its work and made recommendations in July 1995. The second task force is well underway in the development of a regulatory system, but there does not appear to be a sufficient sense of urgency to get the job done.” *See* 142 CONG. REC. S1856 (daily ed. March 12, 1996) (statement of Sen. Hatch, Chairman, Senate Comm. on the Judiciary), *supra* note 30, at S1863. According to Hatch, because the criminal code had gaps that prevented prosecution of an individual who obtained a biological agent under false pretenses, and because anyone could legally possess an agent, waiting a year for final rules was not acceptable and legislative action thus necessary. *See id.* Senator Hatch also noted that regulations developed by the CDC, U.S. Postal Service, U.S. Department of Agriculture, U.S. Department of Commerce, FDA, and U.S. Department of Transportation were developed “with little or no apparent integration” and with narrow purposes in mind. *See id.* at S1862. In underlining that the regulations had not kept pace with scientific advances, the Senator explained that CDC biohazard levels did not reflect changes in agent classification, genetic technology, or the emergence of new strains of organisms. *See id.* at S1863. Finally, Senator Hatch emphasized that the CDC regulations did not take into account potential agent theft and did not attempt to prevent misdirection of agents into the hands of unauthorized individuals. *See id.*

⁶⁶Barry Kellman, *Regulation of Biological Research in the Terrorism Era*, 13 HEALTH MATRIX 159, 160 (Winter 2003); *see generally* Dagan, *supra* note 32. Agents were determined to be of “unique interest” according to their capacity to be used as weapons. *See* Kellman, *Regulation of Biological Research in the Terrorism*, *supra* at 161. The Biological Agents Bill sought primarily to close gaps in the criminal laws that made it difficult to prosecute individuals who accessed or attempted to access pathogens for unauthorized purposes, as well as gaps in federal regulations that allowed unfettered access to the pathogens themselves. *See* Dagan, *supra* note 32, at 553.

⁶⁷18 U.S.C. § 178(1)(A)-(C); *see* 142 CONG. REC. S1856 (daily ed. March 12, 1996) (statement of Sen. Hatch, Chairman, Senate Comm. on the Judiciary), *supra* note 30, at S186218. For the CDC’s earlier definition of etiologic agent, *see supra* note 32. The CDC, for its part, considered the term “etiologic agent” to be extremely similar in nature to the term “biological agent,” noting in Appendix C of its 1999 BMBL that “etiologic agents...[are] closely related terms that are found in the transfer and transportation regulations” (defining both biological and etiologic agent). *See supra* note 44.

CDC's regulatory authority.⁶⁸

a.

The Biological Agents Act directed the CDC to establish and maintain a list of biological agents with the potential to pose a severe health and safety threat to the public.⁶⁹ The Act further delineated four criteria for determining which agents warrant inclusion by the CDC on the list. First, the Act stated that the CDC should consider the agent's effect on human health in the event of exposure.⁷⁰ Second, the CDC should note the degree of contagiousness of the agent, as well as existing methods of transmission to humans.⁷¹ Third, the CDC should evaluate the availability and effectiveness of immunizations and treatments for any illness resulting from infection.⁷² Finally – and perhaps most importantly for the CDC, given the concerns of the scientific community about the inhibition of legitimate research – the CDC must consult with scientific experts representing appropriate professional groups before placing any agent on the list.⁷³

b.

The Biological Agents Act also required the CDC to institute regulations for the establishment and enforcement of safety procedures for the transfer of biological agents.⁷⁴ According to the Act, safety procedures

⁶⁸See Dagan, *supra* note 32, at 553. Although the language of the AEDPA refers to the Secretary of DHHS, the Secretary delegated its authority under the AEDPA to the CDC. See Antiterrorism and Effective Death Penalty Act of 1996, Delegation of Authority, 62 Fed. Reg. 15186 (March 31, 1997) (further affirming or ratifying any actions taken by CDC related to the AEDPA prior to the delegation). In addition to expanding the CDC's role in agent regulation, the AEDPA made two important changes to the criminal code in the area of biological weapons control. First, it amended three sections of the 1989 Biological Weapons Antiterrorism Act to insert "genetically altered products" into the definition of biological agent, to add criminal penalties for attempts, threats, or conspiracies to violate federal biological weapons laws, and to give the government increased authority to seek injunctions against those who threaten to violate federal biological weapons laws. See Dagan, *supra* note 32, at 554-555. Second, it amended the federal statute that criminalizes the use of weapons of mass destruction to include the use of genetically altered biological products. See *id.*

⁶⁹Antiterrorism and Effective Death Penalty Act of 1996, Pub. L. 104-132, 110 Stat. 1214, §511(d)(1)(A) (codified at 42 U.S.C. §242).

⁷⁰*Id.* at §511(d)(1)(B)(i)(I) (codified at 42 U.S.C. §242, later subsumed by P.L. 107-188).

⁷¹*Id.* at §511(d)(1)(B)(i)(II) (codified at 42 U.S.C. §242, later subsumed by P.L. 107-188).

⁷²*Id.* at §511(d)(1)(B)(i)(III) (codified at 42 U.S.C. §242, later subsumed by P.L. 107-188).

⁷³*Id.* at §511(d)(1)(B)(ii) (codified at 42 U.S.C. §242, later subsumed by P.L. 107-188).

⁷⁴*Id.* at §511(e)(1) (codified at 42 U.S.C. §242, later subsumed by P.L. 107-188).

included measures to ensure proper training in handling listed agents, as well as official certification of laboratories storing and disposing of agents and related biological material.⁷⁵ The Act instructed the Secretary of Health and Human Services (“the Secretary”) to institute safeguards to prevent unauthorized access to listed agents for terrorist or criminal purposes and procedures to protect the public in the event of an unlawful transfer.⁷⁶ Because two competing interests were at stake – the interest of the medical and scientific communities in accessing and shipping agents used for diagnostic purposes, and the interest of the public in being adequately protected from attack – the Act sought to ensure that the CDC’s regulations would strike an appropriate balance by stating that the Secretary must guarantee that agents remain available for educational and other legitimate uses.⁷⁷

In order to expedite the CDC’s regulatory mission, the Act required the CDC to establish, within 60 days, a proposed rule.⁷⁸ Final rules were to be promulgated no later than 120 days from enactment of the legislation.⁷⁹

In response to these requirements, the CDC issued a Notice of Proposed Rulemaking on June 10, 1996, based on “the key principles of ensuring protection of public safety without encumbering legitimate scientific and medical research.”⁸⁰ The proposed rule amended existing CDC requirements for the packaging, labeling and transport of etiologic agents, and was designed to establish a system of agent transport safeguards.⁸¹ The rule included new measures to track the acquisition and transfer of biological agents and a process for alerting appropriate authorities in the event of an unauthorized attempt to acquire biological material.⁸² More specifically, the proposed rule provided for the development of a comprehensive list of “select agents,” defined as “those microorganism[s] (virus, bacterium, fungus, rickettsia) or toxin[s]” capable of posing a severe public health threat and subject to regulation under 42 C.F.R. § 72, pursuant to the AEDPA.⁸³ The proposed rule

⁷⁵*Id.* at §511(e)(1)(A), §511(e)(1)(B) (codified at 42 U.S.C. §242, later subsumed by P.L. 107-188).

⁷⁶*Id.* at §511(e)(2), §511(e)(3) (codified at 42 U.S.C. §242, later subsumed by P.L. 107-188).

⁷⁷*Id.* at §511(a)(2) (adequate protection from attack), §511(a)(4) (need for research), §511(e)(4) (agents remain available for educational and legitimate purposes) (codified at 42 U.S.C. §242, later subsumed by P.L. 107-188); *see also* Dagan, *supra* note 32, at 556-557.

⁷⁸Antiterrorism and Effective Death Penalty Act, §511(f)(1) (codified at 42 U.S.C. §242, later subsumed by P.L. 107-188).

⁷⁹*Id.* at §511(f)(2) (codified at 42 U.S.C. §242, later subsumed by P.L. 107-188).

⁸⁰Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents, 61 Fed. Reg. 29327 (June 10, 1996); *see also* Additional Requirements for Facilities Transferring or Receiving Select Agents, 61 Fed. Reg. 55190 (October 26, 1996) (discussing content and goals of proposed rule).

⁸¹Additional Requirements for Facilities Transferring or Receiving Select Agents, 61 Fed. Reg. 55190.

⁸²*Id.*

⁸³*Id.* at 55191.

also provided for the registration of facilities transferring agents, verification procedures such as audits and quality control to ensure compliance, and agent disposal requirements, although it allowed several research and clinical exemptions.⁸⁴ During the 30-day comment period, the CDC received 67 written responses, and over 200 comments.⁸⁵ While a significant majority of the comments requested clarification on the meaning of words or phrases or suggested additions or deletions to the proposed list of select agents, a number focused on the substantive requirements imposed by the regulation.⁸⁶ For example, several comments questioned the continued relevance of the CDC's Biosafety in Microbiological and Biomedical Laboratories ("BMBL") manual and thus the value of incorporating it into the regulation, noting that it provided only "vague guidelines" for the handling of agents.⁸⁷ However, because the CDC believed that the BMBL served as the only nationally and internationally recognized source for biosafety requirements for laboratories, it decided to retain its incorporation in the rule.⁸⁸ Similarly, a number of comments suggested that the CDC base its registration procedures on models used by other entities.⁸⁹ The CDC in fact reviewed models instituted by the Nuclear Regulatory Commission, the National Committee for Clinical Laboratory Standardization, the U.S. Department of Agriculture, the National Institutes of Health, and the American Association for Accreditation of Laboratory Animal Care, and adapted many aspects of these models for its own system, including, for example, on-site inspections, user fees, and registration and transfer requirements.⁹⁰ Finally, in response to several pointed comments, the CDC emphasized that it would provide oral hearings for registration appeals, that the final rule would not preempt other applicable federal regulations, and that the rule was intended to apply to both intrastate and interstate shipment and transfer.⁹¹

The CDC issued its final regulation on October 24, 1996, although the regulation did not become effective until April 15, 1997.⁹² The regulation established the Laboratory Registration/Select Agent Program ("Select Agent Program") at CDC headquarters in Atlanta, Georgia, and added sections 72.6, 72.7, and Appendix A⁹³ to 42 CFR 72. The final regulation had several essential components:

⁸⁴*Id.* at 55190.

⁸⁵*Id.*

⁸⁶*See id.*

⁸⁷*See id.* at 55191.

⁸⁸*See id.*

⁸⁹*See id.*

⁹⁰*See id.*

⁹¹*See id.* at 55191-55192.

⁹²*See id.* at 55190.

⁹³42 C.F.R. § 72, Appendix A lists the select agents monitored by the CDC pursuant to the rule. For a complete account of the current contents of Appendix A, see Appendix 1 of this paper.

a.

The final regulation included a list of 36 “select agents” monitored by the CDC because of their potential to cause substantial harm to human health.⁹⁴ Of these 36 agents, 13 were viruses, 12 toxins, 7 bacteria, 3 rickettsia, and 1 fungi.⁹⁵ Although the final list was ultimately compiled using the criteria delineated in the Biological Agents Act, the CDC based its list primarily on agents whose export from the U.S. was controlled prior to the regulation due to particularly high levels of pathogenicity.⁹⁶ The CDC also consulted with U.S. military and civilian experts and members of the American Society for Microbiology in determining which agents to include or exempt as appropriate.⁹⁷ All materials known or reasonably suspected of containing a select agent were subject to regulation.⁹⁸

b.

All facilities requesting or transferring select agents listed in the regulation, whether commercial suppliers, universities, research institutions, or private individuals, were required to register with the CDC – or with registering entities authorized by the CDC – as capable and equipped to handle biological material at the appropriate Biosafety Level.⁹⁹ Once registered, the regulations provided that each facility would receive a

⁹⁴ See Additional Requirements for Facilities Transferring or Receiving Select Agents, 61 Fed. Reg. 55190, *supra* note 80, at 55199-55200. The select agent list was codified at Appendix A of 42 C.F.R. § 72.

⁹⁵ See *id.*

⁹⁶ *The Threat of Biological Weapons: Hearing Before the Senate Select Comm. on Intelligence*, 105th Cong. (1998) (statement of Dr. Stephen Ostroff, Associate Director of Epidemiologic Science, Centers for Disease Control and Prevention). For a list of the agent criteria delineated in the Biological Agents Act, see *supra* page 16.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ Additional Requirements for Facilities Transferring or Receiving Select Agents, 61 Fed. Reg. 55190, *supra* note 80, at 55196; see Dagan, *supra* note 32, at 558; see also Kellman, *Biological Terrorism: Legal Measures for Preventing Catastrophe*, *supra* note 31, at 450, 452-453. According to the rule, registration involved (1) the provision of sufficient information indicating that the applicant facility was equipped to handle agents at Biosafety Level 2, 3, or 4, depending on the agent and type of work being performed, (2) inspection of the applicant facility at the discretion of the Secretary or the registering entity, (3) issuance of a registration number unique to each facility, (4) collection of a periodic site registration fee, and (5) follow-up inspections as appropriate to ensure that the facility continued to meet approved standards and recordkeeping requirements. Additional Requirements for Facilities Transferring or Receiving Select Agents, 61 Fed. Reg. 55190, *supra* note 80, at 55197, codified at 42 C.F.R. § 72.6(a)(2)(i)-(v). Registration was to be considered effective until relinquished by the facility or withdrawn by the

registration number, which had to be produced to appropriate law enforcement authorities or DHHS officials upon request.¹⁰⁰

c.

Under the new rule, select agents could only be transferred between registered facilities. Each registered facility was required to complete a federally developed form – the CDC EA-101 – before transfer.¹⁰¹ The rule required that the form be signed by both the transferor and the requester, as well as the responsible officials at each facility.¹⁰² A copy of the completed CDC EA-101 was required to be kept on file by each facility for either five years after the date of shipment or five years after the agents were consumed or disposed, whichever was longer.¹⁰³ An additional copy had to be sent to the CDC, or the appropriate registering entity, for documentation.¹⁰⁴ Once the transfer was set in motion, the transferring facility had to comply with the CDC's packaging and shipping requirements.¹⁰⁵ Finally, the requesting facility was required to acknowledge receipt of the agent within thirty-six hours and return a paper copy or facsimile transmission of receipt to the transferring facility within three business days.¹⁰⁶

d.

DHHS Secretary or registering entity. *Id.*, codified at 42 C.F.R. §72.6(a)(3). Registration could be denied on the basis of (1) evidence that the facility was not or was no longer capable of handling covered agents at the applicable biosafety level, (2) evidence that the facility had handled covered agents in a manner contrary to the biosafety level requirements, (3) evidence that the facility had or intended to use agents in a manner harmful to human health, (4) evidence that the facility had not complied with the rule, or (6) failure to pay any required registration fee. *Id.*, codified at 42 C.F.R. §72.6(a)(4)(i)-(v).

¹⁰⁰Kellman, *Biological Terrorism: Legal Measures for Preventing Catastrophe*, *supra* note 31, at 452-453.

¹⁰¹*Id.* at 453; Additional Requirements for Facilities Transferring or Receiving Select Agents, 61 Fed. Reg. 55190, *supra* note 80, at 55196. According to the rule, information required by the CDC EA-101 included (1) the name of the requestor and requesting facility, (2) the name of the transferor and transferring facility, (3) the name of the responsible facility official for the transferor and requestor, (4) the requesting facility's registration number, (5) the transferring facility's registration number, (6) the name of the agent(s) being shipped, (6) the quantities of the agent(s) being transferred (number of containers being transferred and amount per container), and (7) the proposed use of the agent. *Id.* at 55198, codified at 42 C.F.R. § 72.6(d)(1)(i)-(viii).

¹⁰²*Id.*, codified at 42 C.F.R. § 72.6(d)(2).

¹⁰³*Id.*, codified at 42 C.F.R. § 72.6(d)(3).

¹⁰⁴*Id.*, codified at 42 C.F.R. § 72.6(f)(3); *see also The Threat of Bioterrorism in America, Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. 26 (1999) (prepared statement of Dr. Stephen Ostroff).

¹⁰⁵*Id.*, codified at 42 C.F.R. § 72.6(f)(1).

¹⁰⁶*Id.*, codified at 42 C.F.R. § 72.6(f)(2).

To ensure oversight of the transfer process, each facility shipping or receiving a covered select agent was required to designate a responsible facility official, who had to sign each transfer request.¹⁰⁷ Prior to transferring an agent, the facility's responsible official was required to verify that the receiving institution retained a valid, current registration, that the requestor of the agent was in fact an employee, and that the proposed use of the agent was effectively delineated.¹⁰⁸ In the event this information could not be verified, the responsible official had to contact the CDC for assistance.¹⁰⁹

The regulation authorized both the DHHS Secretary and any registering entity to conduct random or for cause inspections of registered facilities to ensure compliance.¹¹⁰ If an inspection indeed occurred, the registered facility had to produce all CDC EA-101 forms and any other records deemed relevant by inspecting officials upon request.¹¹¹ Inspections were authorized for inter- and intra-facility transfers as well as agent disposal procedures.¹¹²

e.

The regulation required that all cultures and agents stocks be securely stored in accordance with applicable laboratory procedures, transferred to another registered facility, or destroyed on-site by autoclaving, incineration, or other approved method of disposal after use.¹¹³ The facility disposing of the agent was further required to notify the DHHS Secretary or registering entity of the agent's destruction.¹¹⁴ Formal notation on the CDC EA-101 form was necessary.¹¹⁵

f.

The CDC regulation provided a number of exemptions. First, an agent otherwise covered by the rule was exempt if the agent was (1) part of a clinical specimen intended for diagnostic, reference, or verification

¹¹³*Id.* at 55199, codified at 42 C.F.R. § 72(h)(3)(ii)(E)(i)(1)(i)-(iii).

¹¹⁴*Id.* at 55199, codified at 42 C.F.R. § 72(h)(3)(ii)(E)(i)(2).

¹¹⁵*Id.*

purposes, (2) a toxin having an LD50 for vertebrates of more than 100 nanograms per kilogram of body weight and used for legitimate medical purposes, inactivated for use as a vaccine, or otherwise detoxified for research, and (3) an exempted strain (i.e., a vaccine strain) pursuant to Appendix A.¹¹⁶ Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 that use biological agents for diagnostic, reference, verification, or proficiency purposes were exempted altogether from registration and transfer requirements.¹¹⁷

g.

The new rule imposed stiff penalties on violators. While individual violators would face a fine of \$250,000, a year in prison, or both in the event of noncompliance, organizational violators could be forced to pay up to \$500,000 per event.¹¹⁸ Moreover, a fraudulent statement or representation on the CDC EA-101 – a government form – would subject the maker of the statement to a fine or imprisonment for up to five years if the statement was by an individual, and a fine if the statement was by an organization.¹¹⁹

The CDC noted in the promulgation of its final rule that it did not expect facilities to incur significant compliance costs.¹²⁰

The changes to the CDC regulation received criticism almost immediately following their adoption. In fact, several critics questioned whether it would be effective at all in limiting unauthorized access to biological

¹¹⁶*Id.* at 55198, codified at 42 C.F.R. § 72(h)(1)(i)-(iii).

¹¹⁷*Id.*, codified at 42 C.F.R. § 72(h)(2). Dr. Ronald Atlas of the American Society for Microbiology explained the reasoning behind the CLIA exemption to the Senate in 2001. According to Atlas, “there is a real difference between the research laboratory and the clinical laboratory. . . the clinical laboratories don’t know when a patient comes in what they are going to isolate. They are not necessarily pre-registered to tell you, We are going to be in possession of anthrax. And in fact under the national laboratory network that we have established for laboratories, the local clinical lab doesn’t really accomplish the identification – that goes on to a public health lab or to the CDC to do. So the clinical lab may in fact be in possession, never know they have the agent.” *Germes, Toxins, and Terror, The New Threat to America: Hearing Before the Subcomm. on Technology, Terrorism, and Government Reform of the Senate Comm. on the Judiciary*, 107th Cong. (2001) (statement of Dr. Ronald Atlas, President, American Society for Microbiology) (responding to questions posed by Senator McConnell).

¹¹⁸Additional Requirements for Facilities Transferring or Receiving Select Agents, 61 Fed. Reg. 55190, *supra* note 80, at 55199, codified at 42 C.F.R. § 72.7.

¹¹⁹*Id.*

¹²⁰*Id.* at 55197. According to the CDC, these costs included minimal administrative costs, such as those associated with telephone calls, mailing, and facsimile transmission. *Id.* The CDC stated that it did not expect facilities to incur any capital costs or significantly increased operating costs. *Id.*

agents and related material.¹²¹ As the critics noted, several aspects of the rule left large loopholes for individuals or terrorist organizations determined to acquire an agent. First, the regulation applied only to transfers of agents undertaken after the institution of the final rule.¹²² Thus, past transfers that may have left agents in the hands of unauthorized users – such as Larry Wayne Harris – were not subject to oversight. Second, clinical laboratories, as compared to medical and research laboratories, were entirely exempted from the scope of the rule, despite the fact that they could contain cultures of potentially dangerous agents.¹²³ Third, the regulations covered lethal agents only.¹²⁴ Less pathogenic agents – for example, salmonella – as well as vaccine strains were left unregulated, even though many of these agents were in fact easier to culture and capable of spreading widespread panic and illness.¹²⁵ Fourth, CDC oversight did not extend to agent culture repositories at laboratories. As the CDC stated in its final rule, if a select agent was stored in a repository prior to the 1997 regulation, no action was required until the agent was transferred.¹²⁶ Consequently, agent theft at improperly secured laboratories remained a viable concern, and the rule did little to encourage university and other research labs to improve inventory controls or bolster culture protection, described by experts as “informal at best.”¹²⁷ Fifth, industry experts noted that the regulation did not address off-the-books trading of lab specimens, a common practice among researchers that accounts for some movement of cultures between the United States and foreign countries.¹²⁸ According to Dorothy Preslar, a former head of the Biological Weapons Verification Project for the American Federation of Scientists, this practice left the door open for individuals to import biological material illicitly.¹²⁹ Finally – and most critically – the CDC regulations governed only transfer, not possession, of a select agent.¹³⁰ Individuals who

¹²¹See *id.* at 55190.

¹²²*Id.* at 55193.

¹²³See *supra* note 117.

¹²⁴Dagan, *supra* note 32, at 561.

¹²⁵To give just two examples: (1) in 1984, the Rajneesh, an Oregon religious cult, contaminated restaurant salad bars with *salmonella* bacteria, sickening at least 751 people, see W. Seth Carus, *The Rajneeshees*, in JONATHAN TUCKER, TOXIC TERROR: ASSESSING TERRORIST USE OF CHEMICAL AND BIOLOGICAL WEAPONS (2000), and (2) in 1996, twelve laboratory workers in Texas were infected with *shigella* bacteria when they ate pastries left anonymously in an employee lounge, see Shellie Kolavic et al., *An Outbreak of Shigella Dysenteriae Type 2 Among Laboratory Workers Due to Intentional Food Contamination*, 278 JAMA 396-398 (1997).

¹²⁶Additional Requirements for Facilities Transferring or Receiving Select Agents, 61 Fed. Reg. 55190, *supra* note 80, at 55193.

¹²⁷Steve Fainaru and Joby Warrick, *Access to Microbes Is Easily Obtained; Federal Oversight of Inventories Lax*, THE WASH. POST, October 28, 2001, at A1.

¹²⁸*Id.*

¹²⁹*Id.* Fainaru and Warrick also cited Mary Gilchrist, President of the Association of Public Health Laboratories, who noted that “some exchanges are as simple as stashing a petri dish into a lab-coat pocket before jetting off to a conference.” *Id.*

¹³⁰The CDC explicitly excluded possessors of biological agents from the scope of its rule, despite comments indicating that such a loophole existed. See Additional Requirements for Facilities Transferring or Receiving Select Agents, 61 Fed. Reg. 55190, *supra* note 80, at 55194.

were not transferors or shippers of an agent remained free to acquire or culture agents on their own.¹³¹ Seth Carus, a nationally recognized expert on biological warfare, described the regulations as a “paperwork drill,” and for would-be terrorists, “a hurdle, but not a big hurdle.”¹³²

The CDC experienced significant implementation difficulties at an early stage. Although the CDC developed a computerized database to track applications, registrations, and select agent transfers, by March 1998, nearly a year after the final regulations became effective, only 60 facilities had completed the registration process, and none had been officially certified.¹³³ In hearings before the House Subcommittee on Oversight and Investigations the following May, Senator Upton emphasized that out of 300 facilities potentially handling biological agents, only 120 had actually registered pursuant to the CDC rule.¹³⁴ On both occasions, the CDC claimed insufficient resources as the source of its implementation failures.¹³⁵ More specifically, the CDC stated that it did not have sufficient funding to hire inspectors, conduct preliminary site visits, or institute follow-up reviews.¹³⁶ The resource crunch was particularly severe because the CDC decided to retain oversight of the facility registration process, rather than delegate this authority to state registering entities as provided in the final rule.¹³⁷ When asked pointedly by Senator Bryan to provide a letter grade describing the adequacy of the infrastructure in place to control access to agents, Dr. Stephen Ostroff,

¹³¹The CDC rule did note that any individual in possession of a “biological agent or toxin . . . for use as a weapon,” as defined in Title 18 of the U.S. Code, would be subject to separate criminal penalties. *See id.*; *see also* 18 U.S.C. § 175. Again, however, the individual had to actually possess the agent for use as a weapon; possession on its own was not a crime, and proof of intent could be a difficult hurdle.

¹³²Rochelle Sharpe, *Germ Warehouse Supplies Raw Material for Research*, WALL ST. J. EUR., March 11, 1998, at 8.

¹³³*The Threat of Biological Weapons: Hearing Before the Senate Select Comm. on Intelligence*, 105th Cong. (1998) (statement of Sen. Kyl). The 60 facilities that had registered included 21 universities, 15 government agencies and 14 commercial enterprises. V. Dion Haynes and Vincent J. Schodolski, *U.S. Tries to Keep Close Tabs on Deadly Shipments*, CHI. TRIB., March 1, 1998, at 4.

¹³⁴*The Threat of Bioterrorism in America, Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. 26 (1999) (statement of Rep. Upton).

¹³⁵*See, e.g., The Threat of Biological Weapons: Hearing Before the Senate Select Comm. on Intelligence*, 105th Cong. (1998) (statement of Dr. Stephen Ostroff, Associate Director of Epidemiologic Science, Centers for Disease Control) (responding to questions posed by Sen. Bryan); *The Threat of Bioterrorism in America, Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. 26 (1999) (statement of Dr. Stephen Ostroff, Associate Director of Epidemiologic Science, Centers for Disease Control) (responding to questions posed by Rep. Burr).

¹³⁶*See The Threat of Biological Weapons: Hearing Before the Senate Select Comm. on Intelligence*, 105th Cong. (1998) (statement of Dr. Stephen Ostroff, Associate Director of Epidemiologic Science, Centers for Disease Control) (responding to questions posed by Sen. Bryan); *see id.* (statement of Sen. Kyl) (posing questions to Col. Franz); *see also* Tony Batt, *Senate Panel Told Biological Threat Very Real*, THE LAS VEGAS REV. J., March 5, 1998, at 1A.

¹³⁷*See id.* (statement of Dr. Stephen Ostroff, Associate Director of Epidemiologic Science, Centers for Disease Control) (responding to questions posed by Sen. Feinstein).

Associate Director for Epidemiological Sciences at the CDC, responded “an A on effort... and probably a D- in resources.”¹³⁸ CDC attempts to raise resource levels by implementing a user fee as part of the application process served only to deter a majority of the 200 outstanding facilities from registering.¹³⁹ During 1998 Senate Intelligence Committee hearings, several Senators chided the CDC for waiting nearly two years to seek additional resources in the face of clear implementation failure, particularly given the importance of the issue and the large number of laboratories that needed to be monitored.¹⁴⁰ The CDC requested and received \$1 million in funding in its 1999 budget, but despite the monetary influx, continued to flounder in its management of the agent registration program.¹⁴¹

Neo-nazi Larry Wayne Harris’ second arrest, on February 18, 1998, shed further doubt on the effectiveness of the CDC Select Agent Program in preventing unauthorized access to deadly pathogens.¹⁴² Harris – the individual who inspired the drafting of the Biological Agents Act – was arrested in Las Vegas, Nevada, after an FBI informant reported that he possessed military-grade anthrax.¹⁴³ Tests later confirmed that the material in Harris’ possession was only a harmless anthrax veterinary vaccine, and charges against Harris were eventually dropped.¹⁴⁴ Nevertheless, Harris’ arrest highlighted many of the problems undergirding the CDC regulatory regime. First, Harris possessed a vaccine strain of anthrax, which was exempt from the CDC’s final rule because of its non-lethal character.¹⁴⁵ Second, although authorities apparently could not determine whether Harris had acquired the agent from a CDC-monitored laboratory, it was clear the

¹³⁸ *Id.* (statement of Dr. Stephen Ostroff, Associate Director of Epidemiologic Science, Centers for Disease Control) (responding to questions posed by Sen. Bryan).

¹³⁹ *Id.* (statement of Colonel David Franz, Deputy Commander, U.S. Army Medical Research and Material Command) (responding to questions posed by Sen. Kyl).

¹⁴⁰ *See id.* (statement of Sen. Kyl); *see id.* (statement of Sen. Bryan). Senator Kyl was particularly concerned about the CDC’s inability to effectively implement its regulations, quering: “why haven’t they been implemented? what priority did you give to the implementation and is the funding that’s finally been asked for this next budget, which presumably would go into effect in October of this calendar year, will that do the job two and one-half years after the fact?” *Id.* (statement of Sen. Kyl) (posing questions to Colonel Franz).

¹⁴¹ *See The Threat of Biological Weapons: Hearing Before the Senate Select Comm.on Intelligence*, 105th Cong. (1998) (statement of Sen. Kyl); *See The Threat of Bioterrorism in America, Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. 26 (1999) (statement of Dr. Stephen Ostroff, Associate Director of Epidemiologic Science, Centers for Disease Control) (responding to questions posed by Rep. Burr, and noting that the CDC believed \$1 million would ensure proper implementation of the CDC’s regulatory mandate); *see id.* (statement of Dr. Ronald Atlas, American Society for Microbiology) (noting, in the context of urging Congress to provide CDC with additional resources in the event of a regulatory expansion, that CDC had not yet fully implemented its current regulations due to lack of sufficient funds).

¹⁴² For details of the Harris arrest, *see generally Anthrax Scheme Suspected, Two Men Seized in Las Vegas Include One Who Tried to Get Plague Bacteria*, BUFFALO NEWS, February 19, 1998, at A1.

¹⁴³ *See Ex-Anthrax Suspect Gets Longer Probation*, THE LAS VEGAS REV. J., March 25, 1998, at 8B.

¹⁴⁴ *Id.*

¹⁴⁵ As previously discussed, the CDC rule covered only lethal agents, despite the fact that vaccines can contain small amounts of virile agent. *See supra* notes 124 and 125.

acquisition occurred without notice on the part of the CDC or law enforcement authorities.¹⁴⁶ Finally, even if the CDC had successfully registered all laboratories at the time of the second Harris arrest, the CDC's final rule did not require individuals like Harris, who possessed agents prior to the final rule's promulgation or cultured agents on their own, to register with the CDC as possessors of a deadly biological agent.¹⁴⁷ Thus, Larry Wayne Harris was again squarely beyond the reach of federal regulatory power, prompting Senator Kyl to note that three years after passage of the AEDPA, "we appear to be in the same position as we were in 1995 with regard to the lack of controls over dangerous biological agents within the United States."¹⁴⁸ Following the Harris arrest, both chambers of Congress instituted a series of reviews of CDC agent controls in an attempt to isolate the reasons behind the apparent failure of the 1996 legislation and 1997 regulations. In early March 1998, the Senate Intelligence Committee held joint hearings with the Judiciary Subcommittee on Terrorism concerning the threat of biological weapons. Senators in attendance chided the CDC for what they viewed as an unacceptable delay in implementation and an ignorance of remaining regulatory gaps.¹⁴⁹ Both Senator Kyl and Senator Bryan repeatedly questioned the CDC as to why the agency still had not registered over two-thirds of domestic laboratories handling biological agents nearly two and a half years after promulgating its final rule, and insisted that the CDC quote a realistic budgetary figure for completing its regulatory program.¹⁵⁰ Senator Feinstein, noting that Larry Wayne Harris obtained agent cultures by using false documentation, interrogated the CDC representative, Dr. Stephen Ostroff, about laboratory security procedures and employee background checks.¹⁵¹ Ostroff, while defending the CDC's verification policy, admitted that the agency did not require criminal background checks and that it would be "extraordinarily difficult" to deter an individual with truly criminal intent from accessing laboratory cultures.¹⁵² Several senators asked for recommendations to tighten the AEDPA and the CDC's regulation.¹⁵³ Ostroff

¹⁴⁶See generally Batt, *supra* note 136.

¹⁴⁷See *supra* note 126; see also Dagan, *supra* note 32, at 560-561.

¹⁴⁸Roger K. Lowe, *Nation Lags in Protection from Biological Terrorism*, THE COLUMBUS DISPATCH, March 8, 1998, at 3B.

¹⁴⁹See *The Threat of Biological Weapons: Hearing Before the Senate Select Comm.on Intelligence*, 105th Cong. (1998) (statement of Sen. Kyl) (noting that "I'm very concerned... that these regulations have still not been fully implemented nearly a year-and-a-half later"); see *id.* (statement of Sen. Feinstein) (opining "I have the very distinct belief that as a nation we remain ill prepared both to counter and to deter a biological or chemical attack by a clandestine perpetrator on a civilian society," and questioning Dr. Ostroff about the existence of background check provisions and specific agents included on or missing from the select agent list).

¹⁵⁰See *id.* (statement of Sen. Kyl) (further querying, in regard to the CDC regulations, "why haven't they been implemented? What priority did you give to the implementation and is the funding that's finally been asked for this next budget, which presumably would go into effect in October of this calendar year, will that do the job two and one-half years after the fact?"); see *id.* (statement of Sen. Bryan).

¹⁵¹See *id.* (statement of Sen. Feinstein).

¹⁵²See *id.* (statement of Dr. Stephen Ostroff, Associate Director of Epidemiologic Science, Centers for Disease Control) (responding to Sen. Feinstein's hypothetical about a determined laboratory employee)

¹⁵³See *id.* (statement of Sen. Shelby) (asking all three panelists what they would consider to be "the two or three most significant steps that Congress could take to strengthen our ability in America to prevent or to diminish the consequences

suggested that the CDC was “open to continually reviewing the efficacy of the regulations as they’ve been promulgated,” and would consider creating safeguards to close “potential loopholes,” but stood behind its final rule, noting that, for example, “continuously just adding on more and more pathogens” would not give “any additional level of assurance.”¹⁵⁴ Attorney General Janet Reno, testifying before both committees in April 1998, corroborated Dr. Ostroff’s statement, noting that the Department of Justice was reviewing potential legislation to strengthen agent controls but emphasizing that any additional safeguards required a “careful balance between public safety and the requirements of legitimate scientific researchers.”¹⁵⁵ In fact, at the close of the joint hearings, the Department of Justice instituted interdepartmental discussions among several executive branch agencies, including the CDC, to develop new legislative proposals in response to the Senate’s criticism.¹⁵⁶

In late 1998, on the heels of the Senate joint hearings, the House Committee on Energy and Commerce – at the request of its Chairman, Representative Bliley – launched a review of the existing regulatory regime governing the possession of biological agents.¹⁵⁷ Concerned that the AEDPA did not make possession of a biological agent unlawful without evidence of intent to use the agent as a weapon, the Committee began interviewing federal officials and non-governmental policymakers in January 1999 in an effort to assess the adequacy of CDC regulations in preventing unauthorized access to agents for both benign and illicit purposes.¹⁵⁸ During the course of the interviews, several law enforcement officials and members of the scientific community expressed concern that the CDC regulations exempted too many entities possessing or using select agents, such as CLIA laboratories.¹⁵⁹ Interviewees further suggested that tightening the regulations would advance public health and federal law enforcement goals. More specifically, the interviewees stated

of biological terrorism, if it occurs?”); *see id.* (statement of Sen. Feinstein) (questioning all three panelists about their recommendations for tightening the biological agent laws).

¹⁵⁴ *See id.* (statement of Dr. Stephen Ostroff, Associate Director of Epidemiologic Science, Centers for Disease Control).

¹⁵⁵ *See Biological Weapons, The Threat Posed by Terrorists: Hearing Before the Subcomm. on Tech., Terrorism, and Gov’t Info. of the Senate Comm. on the Judiciary*, 105th Cong. (1998) (statement of Attorney General Reno) According to a report by the House Committee on Commerce, these concerns had been raised with the Clinton Administration for several years prior to the Committee’s oversight of the problem, but had been

“blocked by concerns raised by the CDC and HHS regarding the impact of tighter regulations on the academic and scientific communities.” H.R. REP. NO. 106-1047 (2001).

¹⁵⁶ *See The Threat of Bioterrorism in America, Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. 15 (1999) (prepared statement of James S. Reynolds, Terrorism and Violent Crime Section, Criminal Division, U.S. Department of Justice).

¹⁵⁷ *See* H.R. REP. NO. 106-1047, *supra* note 155.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.* In fact, it was estimated that approximately 150,000 CLIA labs existed in the domestic United States – providing, theoretically, 150,000 exemptions to the CDC rule. *The Threat of Bioterrorism in America, Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. 42 (1999) (statement of Rep. Burr) (questioning James S. Reynolds of the Department of Justice).

that the CDC regulations should be expanded to cover possession as well as transfer, ensuring governmental knowledge of all legitimate agent users and allowing the CDC to guarantee minimum safety requirements.¹⁶⁰ Interviewees from the Department of Justice and FBI asserted that an expanded registration scheme encompassing possession would serve as a potent law enforcement tool, closing the loophole that allowed questionable possessors who did not acquire or transfer agents from a laboratory to avoid prosecution.¹⁶¹

The review also revealed a surprisingly slow response from the Clinton Administration to rising anxiety about the adequacy of the CDC regulation. Despite Attorney General Reno's 1998 testimony that the Department of Justice recognized gaps in the federal laws pertaining to biological agent control and was "actively reviewing legislative proposals to address [concerns with] federal criminal statutes and CDC regulations," President Clinton's 1999 anti-terrorism initiatives did not include any changes in this area.¹⁶² After release of the Clinton plan, Chairman Bliley contacted both the President and Attorney General Reno, urging the Administration to focus on the prevention of bioterrorism by reviewing all outstanding questions related to access and possession.¹⁶³ The House Committee also notified the Administration in late April that it planned to hold official oversight hearings on the regulation of biological agents and efficacy of CDC efforts.¹⁶⁴ The Committee's pressure paid off. On May 12, 1999, the Administration announced that its omnibus crime bill would contain provisions strengthening the existing legal regime governing the shipment and possession of biological agents.¹⁶⁵ Specifically, the President's crime bill (also known as the "21st Century Crime Bill") included measures to bar unauthorized possession of certain highly lethal biological agents by any individual, to tighten inventory controls, and to prevent particular categories of individuals, such as felons, from

¹⁶⁰H.R. REP. NO. 106-1047, *supra* note 155.

¹⁶¹*See id.*

¹⁶²*Id.* President Clinton's initiatives were announced on January 22, 1999. *Id.*

¹⁶³*Id.* Chairman Bliley's contacts occurred in March 1999. *Id.* Bliley also "reminded Attorney General Reno of her prior testimony on this subject and inquir[ed] into the status of the Department's legislative and regulatory proposals." *Id.*

¹⁶⁴*Id.*

¹⁶⁵*Id.* William F. Raub, Deputy Assistant Secretary for Science Policy at DHHS, testified before the House Committee on Commerce that the President's reasons for including the provisions were as follows: "One, although transfer of select agents between facilities is regulated through Part 72 of Title 42 of the Code of Federal Regulations, the current rule does not cover possession by facilities or individuals when no transfer is involved. Two, individuals who possess hazardous biological materials of a type or in a quantity not justified by a peaceful purpose are a danger to society. Current statutes are insufficient to discourage such behavior. Three, an analogous concern about danger to society and limitations on current statutes exists with regard to individuals who handle hazardous materials knowingly, recklessly, and in conscious disregard of public health and safety. Four, a hoax or other false report regarding hazardous biological materials warrants either civil or criminal penalty, commensurate with the act. Five, the question of who should have access to select agents in research in public health laboratories requires careful attention." *The Threat of Bioterrorism in America, Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. 22 (1999) (prepared statement of William F. Raub, Deputy Assistant Secretary for Science Policy, Office of the Assistant Secretary for Planning and Evaluation, Office of the Secretary of Health and Human Services) (explaining the provisions of the President's omnibus crime bill).

possessing biological agents by instituting background checks.¹⁶⁶

As the Administration continued drafting its crime bill, the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations went forward with its scheduled hearings on the Threat of Bioterrorism in America: Assessing the Adequacy of Federal Laws Relating to Dangerous Biological Agents. Convened on May 20, 1999, the hearings involved testimony from two panels of witnesses with divergent interests. The first panel, composed of government representatives from the DOJ, FBI, CDC, and DHHS, unanimously expressed support for expanding CDC agent regulation to encompass possession, as well as transfer, of highly lethal agents. While the panel noted some improvements in the CDC's implementation of the 1997 regulations since the 1998 Senate joint hearings – for example, the CDC was revising its laboratory biosafety guidelines to include physical security and had begun preliminary inspections of a dozen registered facilities – it also underlined that the problem of unauthorized access to biological material remained largely unaddressed by existing CDC rules. In the words of Representative Stupak, the regulations were “working well for the narrow purposes for which they were intended,” but were not adequately addressing their broader purpose of preventing bioterrorism.¹⁶⁷ The second panel, which consisted of non-governmental witnesses from the academic and scientific communities, conceded the need for tighter possession controls but held fast to its assertion that regulation should not inhibit legitimate research.¹⁶⁸ As Dr. Ronald Atlas argued, in responding to the terrorist threat, government “must minimize any adverse impact on basic bioclinical and diagnostic research related to infectious diseases.”¹⁶⁹ Any new legislation or expansion of the CDC regulation, the second panel stated, must continue the delicate balancing between scientific and public safety concerns begun with the AEDPA.¹⁷⁰ According to several of the panelists, this goal could be achieved by mandating increased laboratory security but leaving responsibility for compliance in the hands

¹⁶⁶H.R. REP. NO. 106-1047, *supra* note 155. House Commerce Committee hearings conducted a week after the announcement suggested that the Administration was still uncomfortable with its own proposals in this area. *See The Threat of Bioterrorism in America, Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. 11 (1999) (prepared statement of Rep. Stupak). According to Rep. Stupak, the proposal seemed “to require a massive new regulatory scheme that is so controversial inside the administration that it forced major revisions in the CDC’s testimonies. . . and delayed receipt of the Justice Department, FBI, and HHS testimony until close to midnight [the day before the hearings].” *Id.*

¹⁶⁷*Id.* at 10. Chairman Bliley concurred, noting that “we permit anyone in this country – including felons, foreign nationals from sensitive countries, and members of extremist groups – to lawfully possess even the most deadly biological agents. . . they don’t even have to register with any Federal agency or gain government approval to possess them.” *Id.* at 5-6 (statement of Chairman Bliley).

¹⁶⁸H.R. REP. NO. 106-1047, *supra* note 155.

¹⁶⁹*The Threat of Bioterrorism in America, Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. 48 (1999) (statement of Ronald M. Atlas, Co-Chair, Task Force on Biological Weapons Control, American Society for Microbiology).

¹⁷⁰*Id.* at 49.

of individual institutions.¹⁷¹ The second panel also warned against instituting background checks for laboratory employees or restricting access to pathogens by foreign nationals, highlighting that as many as 25-30% of all graduate students working in laboratories – and recruited for that specific purpose – were not U.S. citizens.¹⁷²

At the House hearings, the CDC was questioned for the first time about its institutional competence as a regulatory agency – a discussion that would later resurface during debate over the establishment of the Department of Homeland Security in 2002. Representative Stupak noted that the shipping regulation for agents, revised by the CDC in 1971 and last updated in response to the AEDPA in 1997, was the first – and only – regulation the CDC had ever issued.¹⁷³ As both Stupak and Representative Waxman underlined, the CDC had not historically been a regulatory agency, and the CDC clearly had a strong desire, manifested throughout its testimony between 1996 and 1999, to hold paramount its scientific relationship with laboratories as legitimate research centers rather than as regulated entities.¹⁷⁴ In suggesting development of a new, separate agency to handle biological agent regulation, Congressman Stupak warned against placing additional burdens on the CDC in areas where the CDC may not be properly trained.¹⁷⁵ Representative Waxman issued a more dire critique, stating that requiring the CDC to undertake inspection and verification duties, including background checks, was inconsistent with the CDC’s mission of public health surveillance and disease prevention.¹⁷⁶ As Waxman rightly explained, mandating that the CDC prioritize its regulatory role forced the agency to expend fewer resources in other areas of bioterrorism prevention – like outbreak detection – better suited to the CDC’s capabilities.¹⁷⁷ Though defensive of its success as a regulatory body, the CDC admitted tension between its role as a regulator and champion of public health.¹⁷⁸ The CDC

¹⁷¹ See, e.g., *id.* at 52 (prepared statement of Ronald M. Atlas, Co-Chair, Task Force on Biological Weapons Control, American Society for Microbiology) (noting that “the DHHS/CDC, acting in cooperation with the scientific and biomedical communities, and with public notice and input, should establish the rules and provide for governmental monitoring. . . however, the registered institution must be responsible for assuring compliance with mandatory procedures and for assuring fully appropriate biosafety mechanisms, including appointment of a responsible official to oversee institutional compliance with biosafety requirements”).

¹⁷² *Id.* at 67 (statement of Dr. Ronald Atlas) (responding to questions posed by Rep. Stupak).

¹⁷³ *Id.* at 4 (statement of Rep. Stupak).

¹⁷⁴ *Id.* at 4-5 (statement of Rep. Stupak) (noting that the CDC is “a premiere, public-health research agency with no expertise in regulatory or law enforcement,” and asserting that the CDC had a “strong desire to keep paramount its collaborative scientific relationship with the laboratories”); see *id.* at 10 (prepared statement of Rep. Waxman) (stating that he feared “burdening CDC with new regulatory duties of inspection and verification” that would be “inimical to their collaborative work with the research community here and abroad”).

¹⁷⁵ *Id.* at 5 (statement of Rep. Stupak).

¹⁷⁶ *Id.* at 10 (prepared statement of Rep. Waxman).

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 33 (statement of Dr. Stephen Ostroff, Associate Director of Epidemiologic Science, Centers for Disease Control). In response to Rep. Burr’s query as to whether the CDC was “comfortable” in its new role, Dr. Ostroff stated that the CDC “[has] attempted, to the best of our abilities, to implement the regulations and carry them

forth. . . I think it has been obvious in some of the statements that it has not been easy for us to do this, because it is a

specifically noted that it did not consider itself to be an inspection agency like the FDA, and stated that it often must collaborate with the same non-governmental researchers it regulates to solve complex scientific issues and prevent the spread of infectious disease.¹⁷⁹ According to Dr. Ostroff, the regulatory framework developed in the 1997 final rule “adversely impacted the longstanding working relationships” of the CDC with members of the scientific community.¹⁸⁰ Nevertheless, many in the scientific community actively argued that the CDC was indeed uniquely suited to carry out its regulatory function. In his testimony before the committee, Dr. Atlas of the American Society for Microbiology maintained that the CDC and DHHS were the only federal entities that possessed the institutional knowledge and expertise necessary to effectively oversee the transport, storage, and use of select agents, and to correctly balance the interests of the government in regulation and researchers in scientific freedom.¹⁸¹ Panelists Preslar and Connell, representing the Federation of American Scientists and the academic community, respectively, supported Atlas’ conclusion.¹⁸² As the CDC scrambled in the ensuing months to respond to the congressional criticism, it also began a full survey of the agents it believed should be targeted by its anti-bioterrorism efforts. In June 1999, the CDC convened a group of academic infectious disease experts, public health authorities, DHHS representatives, civilian and military intelligence experts, and law enforcement officials to review and comment on the threat potential of various biological agents.¹⁸³ To determine an agent’s “threat potential,” the group looked to 1) the amount of illness and death anticipated from infection with the agent, 2) the agent’s delivery potential to large populations, 3) the level of fear and potential civil disruption associated with the agent, and 4) any special public health preparedness needs in the event of large-scale infection, such as stockpile requirements, enhanced surveillance, or diagnostic tools.¹⁸⁴ The group then analyzed publicly available and classified lists

relatively nontraditional role for us to take.” *Id.*

¹⁷⁹*Id.* at 33.

¹⁸⁰*Id.* at 23.

¹⁸¹*Id.* at 49 (statement of Ronald M. Atlas, Co-Chair, Task Force on Biological Weapons Control, American Society of Microbiology). In later testimony, Dr. Atlas asserted that “the CDC is the only federal agency with the expertise and experience to act quickly and competently in this area. Further, and very importantly, the CDC currently possesses the confidence of the scientific community that it will act responsibly to balance the interests of preventing bioterrorism and advancing research in the area of infectious diseases and clinical diagnostic measures.” *Germs and Toxins as Domestic Terrorist Threats: Hearing Before the Senate Comm. on the Judiciary* 107th Cong. (2001) (statement of Ronald M. Atlas, President, American Society of Microbiology).

¹⁸²The Threat of Bioterrorism in America, Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce, 106th Cong. 63 (1999) (statement of Nancy D. Connell, Assistant Professor of Microbiology and Molecular Genetics, University of Medicine and Dentistry of New Jersey, New Jersey Medical School) (responding to questions posed by Rep. Burr); *id.* (statement of Dorothy Preslar, Federation of American Scientists) (responding to questions posed by Rep. Burr, but further noting that the CDC should receive interagency input).

¹⁸³*Developing Countermeasures to Biological Attacks: Hearing Before the House Select Comm. on Homeland Security*, 108th Cong. (2003) (statement of Ali Khan, Associate Director for Science Division of Parasitic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention).

¹⁸⁴*Id.*

in an effort to establish high-priority agents for regulation.¹⁸⁵ After the meeting, CDC staff attempted to identify objective indicators that could be used to further delineate high impact agents.¹⁸⁶ Finally, three informal categories of agents were established based on the criteria employed by the group and the CDC staff: categories A, B, and C.¹⁸⁷ Category A agents were those that had the greatest potential for mass casualties and a negative public health impact, and required the most involved preparedness efforts, such as improved surveillance and stockpiling of medication.¹⁸⁸ Category A agents also had a high likelihood of large-scale dissemination and could cause significant civil disruption.¹⁸⁹ By contrast, Category B agents, while also possessing some potential for large-scale dissemination, were those agents that caused a lesser degree of illness and death and thus would have a lower public health impact.¹⁹⁰ Category B agents required fewer preparedness efforts and included some agents of particular concern for the food and water supply.¹⁹¹ Category C was limited to those agents that did not present a high bioterrorism risk but were of possible future concern.¹⁹² Upon completion of the categorization, the CDC chose not to amend or revise its 1997 select agent list, or to apply this “categorization” concept to the Select Agent Program.¹⁹³ It did, however, use its review framework to guide state and local preparedness programs, to determine the formulary for its Strategic National Stockpile, and to determine reagents and protocols for the Laboratory Response Network.¹⁹⁴

With the CDC finishing its agent review, the House Commerce Committee continued to pressure the Clinton Administration to respond to its concerns with substantial reform of existing biological agent regulations. In an August 9, 1999 letter to Attorney General Reno, Chairman Bliley stated that he was “concerned that we will have to wait until the actual new millennium (2001), and a new Administration, before we see some concrete action on this front.”¹⁹⁵ In December, the Administration sent its 21st Century Crime Bill

¹⁸⁵ *Id.* According to Khan, only individuals with appropriate clearance reviewed classified lists. *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² *Id.*

¹⁹³ A Westlaw search of the Federal Register from 1998-2004 returned no instances of CDC revision of its rule in response to the critical agent review. Moreover, while the CDC did not provide a reason for refusing to revise the select agent list, it would appear that cost considerations were a prime factor.

¹⁹⁴ *Developing Countermeasures to Biological Attacks: Hearing Before the House Select Comm. on Homeland Security*, 108th Cong. (2003) (statement of Ali Khan, Associate Director for Science Division of Parasitic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention). According to Khan, “the presence of anthrax on this list led to the focused preparedness efforts on drug stockpiles and diagnostic tests that were available during the 2001 anthrax attack.” *Id.*

¹⁹⁵ *Bliley Blasts Reno, Administration for Failure To Address Bio-Terrorism Threats*, PR NEWswire, Aug. 10, 1999.

– complete with revisions to the biological agent laws – to Congress.¹⁹⁶ However, despite a great deal of bipartisan support, the legislation died in committee due to strong opposition from universities, who claimed the measures would severely restrict academic freedom.¹⁹⁷ Several other bills introduced in the House and Senate between 1999 and 2001 met the same fate.¹⁹⁸ Thus, Bliley’s statement ultimately rang true: only after the federal government was faced with the fallout from September 11, 2001, did sufficient momentum emerge to finally tighten the CDC regulations.

IV.

The September 11, 2001 attacks on the World Trade Center and Pentagon highlighted America’s vulnerability to terrorism and served as a call to arms for legislators determined to ensure the country’s physical security. For officials concerned with the potential for a bioterrorist strike, the two months following the al-Qaeda attacks appeared to represent the worst-case scenario, as an unidentified assailant used the United States Postal Service to disseminate anthrax spores to media outlets, congressional officials, and ordinary citizens along the East Coast. By the time the anthrax mailings ceased in mid-November, 5 people were dead and another 17 infected.¹⁹⁹ Although the source of the anthrax could not be definitively traced, the FBI hypothesized that the spores were obtained from domestic – perhaps even federal – laboratories.²⁰⁰ In light of the FBI accusations, Congress accelerated its pre-September 11 calls for an overhaul of the CDC regulations and other laws governing the transfer and use of select biological agents.²⁰¹ In fact, only six weeks after

¹⁹⁶H.R. REP. NO. 106-1047, *supra* note 155. The Administration’s bill was introduced in December 1999. *Id.*

¹⁹⁷Fainaru and Warrick, *supra* note 127, at A1.

¹⁹⁸*See, e.g.*, H.R. 3160, 107th Cong. (2001) (the “Bioterrorism Enforcement Act of 2001,” introduced by Rep. Tauzin); S. 1706, 107th Cong. (2001) (the “Bioweapons Control and Tracking Act of 2001,” introduced by Sen. Harkin). Senators Feinstein and Gregg also attempted to amend the FY 2002 Defense Department spending bill to include measures related to the regulation of biological agents. Press Release, Dianne Feinstein, Senate Appropriations Committee Approves Feinstein-Gregg Measure to Require Strict Certification of Labs to Help Combat Bioterrorism (Dec. 4, 2001) (on file with the Federal Document Clearinghouse). Although the Senate Appropriations Committee approved the amendment, the committee’s version failed in a floor vote. *See* Bill Summary & Status File for P.L. 107-117, THOMAS, available at thomas.loc.gov, last visited on April 5, 2004.

¹⁹⁹UNITED STATES GENERAL ACCOUNTING OFFICE, HOMELAND SECURITY: CDC’S OVERSIGHT OF THE SELECT AGENT PROGRAM, GAO-03-315R, at 1 (Nov. 22, 2002).

²⁰⁰*Id.*

²⁰¹The anthrax mailings did not provide the only signal that the CDC program was not working. For example, a February 2001 investigation by the Inspector General of the Department of Energy had revealed several microbe exchanges – including transfers of anthrax, brucellosis, and plague – that had not been reported to the CDC as required under the 1997 regulation.

the September 11 attacks, President Bush signed into law the USA Patriot Act of 2001, which restricted felons, drug users, illegal aliens, aliens from countries deemed supporters of international terrorism, and other “persons of interest” from shipping and transporting select agents in interstate commerce pursuant to the CDC final rule.²⁰² However, it was not until the Public Health Security Bioterrorism Preparedness and Response Act of 2002 (“PHSBPRA”), which built on the restrictions imposed by the Patriot Act, that Congress again redefined the scope of CDC authority and expanded its regulatory responsibilities.

Enacted on June 12, 2002, the PHSBPRA represented a near-unanimous, bipartisan response to the per-

Similarly, another lab “had provided ‘potentially misleading information’ to the CDC about whether it was qualified to handle certain kinds of dangerous pathogens.” Joby Warrick, ‘No One Asked Questions:’ Scientists Recount U.S. Biodefense Labs’ Security Lapses, THE WASH. POST, Feb. 19, 2002, at A1.

²⁰²Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA Patriot Act) Act of 2001, P.L. No. 107-56, 115 Stat. 272 (hereinafter, “USA Patriot Act”) § 817 (codified at 18 U.S.C. § 175a). The USA Patriot Act’s language specifically stated that: “(a) no restricted person described in subsection (b) shall ship or transport in interstate or foreign commerce, or possess in or affecting commerce (sic), any biological agent or toxin, or receive any biological agent or toxin that has been shipped or transported in interstate or foreign commerce, if the biological agent or toxin is listed as a select agent in subsection (j) of section 72.6 of title 42, Code of Federal Regulations, pursuant to section 511(d)(1) of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132), and is not exempted under subsection (h) of such section 72.6, or appendix A of part 72 of the Code of Regulations.” *Id.* at § 817(2)(a). The term “select agent” was defined in section to exclude “any such biological agent or toxin that is in its naturally-occurring environment, if the biological agent or toxin has not been cultivated, collected, or otherwise extracted from its natural source.” *Id.* at § 817(2)(b)(1). The term “restricted person” was defined to mean (A) any individual under indictment for a crime punishable by imprisonment for a term exceeding 1 year; (B) any individual convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year; (C) a fugitive from justice, (D) an unlawful user of any controlled substance, (E) an illegal alien, (F) an individual adjudicated as a “mental defective” or “committed to any mental institution,” (G) an alien who is a national of a country deemed by the Department of State to be a supporter of international terrorism, and (H) an individual discharged from the Armed Services of the United States under dishonorable conditions. *Id.* at § 817(2)(b)(2)(A)-(H). Violators of the USA Patriot Act are subject to fines and prison terms of up to 10 years. *Id.* at § 817(2)(c). An amendment to the Act, offered by Rep. Scott, would have narrowed the list of persons restricted from possessing biological agents by changing the definition of persons restricted “due to indictment for a crime,” to persons “indicted for a Federal terrorism offense.” H.R. REP. NO. 107-236, pt. 1 (2001). The amendment failed by voice vote. *Id.* Rep. Scott’s amendment would also have prohibited any alien from a country recognized by the State Department as supporting international terrorism, as well as anyone forbidden to own firearms under U.S. law, from possessing, receiving, or transporting a biological agent or toxin. *Id.* Though the “restricted user” provision of the Patriot Act had been debated in committee several years prior to the anthrax mailings, and had even been the subject of proposed legislation a year before its passage, many in the scientific community were caught by surprise. *See, e.g., The Threat of Bioterrorism in America, Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. (1999) (discussing the possibility of restricting access to agents by specific groups of individuals, including felons, and noting that the President’s 21st Century Crime Bill would include measures designed to limit agent access). Specifically, according to several scientific organizations, the Patriot Act’s “blanket restriction” on access to pathogens by individuals from terrorist countries working in the U.S. may prevent scientists from undertaking work with potential public health or national security benefits. *Germes, Toxins, and Terror, The New Threat to America: Hearing Before the Subcomm. on Technology, Terrorism, and Government Reform of the Senate Comm. on the Judiciary*, 107th Cong. (2001) (statement of Dr. Ronald Atlas, President, American Society for Microbiology) (responding to questions posed by Sen. Feinstein). Representatives of the scientific community raised these concerns in congressional hearings throughout the fall of 2001, and lobbied for a waiver to be included in the PHSBPRA. *See id.* Despite academic resistance to the Patriot Act’s provisions, the CDC noted that the number of entities affected by the restriction would be limited, and the scientific community itself admitted that the burden would be “minimal.” H.R. REP. NO. 107-236, pt. 1 (2001); *see also* David Malakoff and Martin Enserink, *New Law May Force Labs to Screen Workers*, 24 SCIENCE 971 (2001).

ceived threat of biological attack as a means of mass-casualty terror in the 21st century.²⁰³ In contrast to the 1996 AEDPA, which was designed primarily to oversee the movement of pathogens, the PHSBPRA had a substantially broader objective: to monitor the distribution and use of agents on a national level.²⁰⁴ The legislation, which grew out of a DHHS bill submitted to Congress in October 2001, as well as several independent proposals advanced in the House and Senate in October and November 2001, was designed to tighten government supervision of agent repositories to bar unauthorized access to, and theft of, select agents.²⁰⁵ Throughout the fall of 2001, congressional hearings – picking up where the House Energy and Commerce Committee 1999 review left off – had focused on the failure of the 1997 CDC final rule to prevent the anthrax mailings.²⁰⁶ Specifically, Congress questioned whether the CDC’s regulatory regime could ever be truly effective if it did not involve oversight of agent possession, criticized the number of exemptions available under the rule for clinical laboratories, and noted the need for better verification measures to monitor compliance.²⁰⁷ The PHSBPRA’s language vis-à-vis biological agents, a compromise between competing House and Senate versions of H.R. 3448, the legislation’s originator bill, thus sought to close many of the loopholes identified in the AEDPA and resulting CDC regulation.²⁰⁸ Subsuming the provisions of the 1996

²⁰³The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594 (codified at 42 U.S.C. § 262a). The House approved the legislation on May 22, 2002 on a vote of 425-1; the Senate followed on May 23, 2002 with a 98-0 vote. *Congress Approves Wide-Ranging Bioterrorism Preparedness Bill*, CIDRAP NEWS, May 24, 2002, available at <http://www.cidrap.umn.edu/cidrap/content/bt/bioprep/news> (last visited April 5, 2004).

²⁰⁴Kellman, *Regulation of Biological Research in the Terrorism Era*, *supra* note 66, at 162.

²⁰⁵For a legislative history of the PHSBPRA, see Bill Summary & Status File for H.R. 3448, THOMAS, available at thomas.loc.gov, last visited on April 5, 2004, as well as The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594, 107 CIS Legis. Hist. P.L. 188; for a concise explanation of the origins of H.R. 3448, the legislation’s derivative bill, see Christine Kirk, *H.R. 3448, Related Legislation, and the FDA’s Expanding Role in Preventing and Responding to Biological Attack* (on file with Peter Barton Hutt, Partner, Covington & Burling) (further noting the legislation’s initial genesis in a bill supported by the Bush Administration); see also *Germes and Toxins as Domestic Terrorist Threats: Hearing Before the Subcomm. on Technology, Terrorism, and Government Information of the Senate Comm. on the Judiciary*, 107th Cong. (2001) (statement of Claude Allen, Deputy Secretary, Department of Health and Human Services (noting that Secretary Thompson developed a draft bill to improve DHHS ability to prevent and respond to bioterrorist threats, the “HHS Bioterrorism Prevention and Emergency Response Act of 2001,” presented to Congress for full consideration in November 2001). For information on predecessor bills, see The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594, 107 CIS Legis. Hist. P.L. 188.

²⁰⁶See, e.g., *Germes and Toxins as Domestic Terrorist Threats: Hearing Before the Subcomm. on Technology, Terrorism, and Government Information of the Senate Comm. on the Judiciary*, 107th Cong. (2001).

²⁰⁷See, e.g., *id.* (statement of Sen. Feinstein) (noting that the existing CDC registration system allowed a number of exemptions, and questioning the appropriateness of the exemptions in light of the anthrax mailings); *id.* (statement of Sen. Feinstein) (highlighting the lack of a verification process for agent disposal).

²⁰⁸In the words of Senator Upton, “this bill will . . . slam shut some gaping loopholes in our regulation of the possession of chemical and biological agents that could be used to launch attacks.” 147 CONG REC H9195 (statement of Sen. Upton). The House and Senate proposed competing versions of the PHSBPRA. See Kirk, *supra* note 996, at 6; see also Bill Summary & Status File for H.R. 3448, THOMAS, available at thomas.loc.gov, last visited on April 5, 2004. While the House passed its version, H.R. 3448, on Dec. 12, 2001, the Senate insisted on a complete substitution of its bill, S. 1765, the “Bioterrorism Preparedness Act of 2001,” into H.R. 3448 by amendment. Kirk, *supra* note 205, at 6. Thus, the Senate passed its amended version unanimously on Dec. 20, 2001. *Id.* The differences between the two bills were eventually ironed out in committee. See H.R. REP. NO. 107-481, 118-119 (2002); see also Bill Summary & Status File for H.R. 3448, THOMAS, available at thomas.loc.gov, last visited on April 5, 2004.

AEDPA, the PHSBPRA, in Title II, Subtitle A imposed new registration requirements on possessors and users of select agents, and increased the CDC's supervision of laboratories and other facilities possessing, using, and transferring select agents.²⁰⁹ In doing so, the PHSBPRA significantly expanded the CDC's regulatory authority in the area of agent controls:

a.

i.

The PHSBPRA instituted a number of changes to the CDC's oversight of its select agent list. First, the PHSBPRA altered the criteria for determining which agents merit inclusion on the list.²¹¹ While preserving the content of the original AEDPA guidelines for classifying select agents, the PHSBPRA instituted an additional, blanket guideline encompassing "any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate."²¹² Just as the CDC was required by the AEDPA to consult with professional groups before placing an agent on the list, the PHSBPRA directed the CDC to consult with "appropriate Federal departments and agencies," as well as with scientific experts representing professional groups – including those with a pediatric focus – before finalizing its agent list.²¹³ The CDC had to conduct, at a minimum, a biennial review of the list, and was required to republish the list as necessary to comply with the PHSBPRA provisions.²¹⁴ According to the Conference Report, the CDC retained flexibility to impose varying levels of security requirements for select agents based on their level of threat to the public.²¹⁵

²⁰⁹ See The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594 (codified at 42 U.S.C. § 262a); see also H.R. REP. NO. 107-481, 45. Although the language of the PHSBPRA refers to the Secretary of DHHS, the Secretary delegated its authority under the PHSBPRA to the CDC.

²¹¹ See *id.* at § 201(a)(1)(B)(i) (later codified at 42 U.S.C. § 242a(a)(1)(B)).

²¹² *Id.* at § 201 (a)(1)(B)(i)(IV) (later codified at 42 U.S.C. § 242a(a)(1)(B)(IV)). For an explanation of the factors the CDC was required to consider when listing a select agent pursuant to the AEDPA, see *supra* page 16.

²¹³ *Id.* at § 201 (a)(1)(B)(ii) (later codified at 42 U.S.C. § 242a(a)(1)(B)(ii)).

²¹⁴ *Id.* at § 201 (a)(2) (later codified at 42 U.S.C. § 242a(a)(2)).

²¹⁵ H.R. REP. NO. 107-481, 199.

ii.

The PHSBPRA expanded the CDC's regulation of agent transfers to provide for the enforcement of procedures governing the possession and use of select agents, and required any entity or individual possessing regulated pathogens to register with the CDC.²¹⁶ All possessors were further required to have a legitimate purpose in possessing, using, or transferring an agent.²¹⁷ Registration involved disclosing to the CDC information regarding the agent's "character," including its source.²¹⁸ The CDC was directed to establish a national database of the names and locations of registered entities and individuals, as well as a list of the agents each entity possessed, presumably to facilitate their identification and traceability.²¹⁹ The CDC was also charged with notifying all possessors of its new mandate within 60 days of the legislation's enactment.²²⁰

iii.

The PHSBPRA directed the CDC to establish, in consultation with the Attorney General, specific security requirements for registered facilities.²²¹ These security requirements were to include measures to ensure access only by researchers with a "legitimate need" to use or handle agents, as well as to deny access to certain individuals, including those defined as "restricted individuals" under the Patriot Act (for example, students or researchers from countries considered sponsors of terrorism) and those "reasonably suspected of committing Federal crimes of terrorism."²²² Registered entities were required to submit the names of all individuals with official access to the agent to the CDC and the Attorney General, as well as identifying information for each individual.²²³ Once supplied with this information, the Attorney General was

²¹⁶The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594, §§ 201(c)-(d) (codified at 42 U.S.C. § 262a(c)-(d)).

²¹⁷*Id.* at § 201(d)(1) (later codified at 42 U.S.C. § 242a(d)(1)).

²¹⁸*Id.* at § 201(d)(2) (later codified at 42 U.S.C. § 242a(d)(2)).

²¹⁹*Id.*; *see also* House Committee on Energy and Commerce Section-by-Section Analysis of Public Health Security and Bioterrorism Response Act of 2001, available at <http://energycommerce.house.gov/107/drafts/3448section.htm>.

²²⁰House Committee on Energy and Commerce Section-by-Section Analysis of Public Health Security and Bioterrorism Response Act of 2001, available at <http://energycommerce.house.gov/107/drafts/3448section.htm>.

²²¹*See* The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594, § 201(e) (later codified at 42 U.S.C. § 262a(e)).

²²²*Id.* at §§ 201(e)(2)(A) and (e)(2)(C) (later codified at 42 U.S.C. § 242a(e)(2)(A), (e)(2)(C), and (e)(2)(D)).

²²³*Id.* at § 201(e)(2)(B) (later codified at 42 U.S.C. § 242a(e)(2)(B)).

permitted to employ criminal, immigration, and national security databases to guarantee that registered individuals met all conditions for access, as long as the Attorney General notified the Secretary promptly of its results.²²⁴ The CDC was required to notify registered entities promptly in the event of denial.²²⁵ The legislation directed the CDC to include provisions for expedited review of an individual's qualifications in its regulations, and allowed the CDC to provide technical assistance to registered entities to improve security and guard against the loss or theft of agents.²²⁶ In the event of loss or theft, a registered entity or individual was required to notify the CDC and federal, state, and local law enforcement agencies.²²⁷ Similarly, in the event of an agent release outside of the biocontainment area of a facility, the registered entity must contact the CDC and Secretary, who may in turn contact law enforcement authorities, the Secretary of Agriculture, or other federal agencies as appropriate.²²⁸

iv.

In contrast to the AEDPA, the PHSBPRA provided for review of CDC decisions to deny an individual access to an agent or to deny or revoke registration privileges by the Secretary.²²⁹ The legislation also allowed the Secretary – and, if applicable, courts – to consider ex parte information if disclosure of that information would harm national security interests.²³⁰

v.

As in the AEDPA, the PHSBPRA authorized the CDC to inspect registered individuals or entities to ensure compliance with CDC regulations.²³¹

²²⁴*Id.* at §§ 201(e)(3)(A)-(C) (later codified at 42 U.S.C. § 242a(e)(3)(A)-(C)).

²²⁵*Id.* at § 201(e)(4) (later codified at 42 U.S.C. § 242a(e)(4)).

²²⁶*Id.* The requirements for expedited review were located at § 201(e)(5) (later codified at 42 U.S.C. § 242a(e)(5)). *Id.* The provisions regarding technical assistance were located at § 201(e)(9) (later codified at 42 U.S.C. § 242a(e)(9)). *Id.*

²²⁷*Id.* at § 201(e)(8) (later codified at 42 U.S.C. § 242a(e)(8)).

²²⁸*Id.* at § 201(j) (later codified at 42 U.S.C. § 242a(j)).

²²⁹*Id.* at § 201(e)(7)(i) (later codified at 42 U.S.C. § 242a(e)(7)(i)).

²³⁰*Id.* at § 201(e)(7)(ii) (later codified at 42 U.S.C. § 242a(e)(7)(ii)).

²³¹*Id.* at § 201(f) (later codified at 42 U.S.C. § 262a(f)).

vi.

Despite strong congressional criticism of existing CDC exemptions, the PHSBPRA maintained the immunity of clinical laboratories from the CDC rule.²³² However, the PHSBPRA did narrow the CLIA exemption, asserting that CLIA laboratories must report select agents identified during the diagnosis and verification process to the CDC and law enforcement authorities, and must destroy those agents pursuant to CDC regulation.²³³ The legislation also exempted certain products containing select agents, provided the products were cleared, approved, licensed, or registered pursuant to the Federal Food, Drug, and Cosmetic Act, the Virus-Serum-Toxin Act, or the Federal Insecticide, Fungicide, and Rodenticide Act, or deemed “investigational” under a Federal Act.²³⁴ Finally, the PHSBPRA allowed the CDC or Secretary to temporarily exempt an entity or individual from compliance with the CDC regulations in the event of a public health or agricultural emergency.²³⁵

vii.

²³²*Id.* at § 201(g)(1)(A)-(B) (later codified at 42 U.S.C. § 262a(g)(1)(A)-(B)). Although many arguments were raised for and against inclusion, the legislation’s exemption of CLIA laboratories appears to be largely practical. As Ronald Atlas, President of the American Society for Microbiology, explained: “there are tens of thousands of CLIA-certified laboratories – probably something like 150,000 diagnostic laboratories in the United States. If we begin registering all of those who don’t really possess the agents, then I think we have a mammoth bureaucratic nightmare ahead of us that doesn’t allow us to focus the attention where it needs to be focused.” *Germs, Toxins, and Terror, The New Threat to America: Hearing Before the Subcomm. on Technology, Terrorism, and Government Reform of the Senate Comm. on the Judiciary*, 107th Cong. (2001) (statement of Dr. Ronald Atlas, President, American Society for Microbiology) (responding to questions posed by Sen. Feinstein). Nevertheless, some researchers believed that the CDC exemption was unwarranted given the goals of the regulation. David Malakoff, *Security Rules Leave Labs Wanting More Guidance*, 299 SCIENCE 1175 (Feb. 2003). According to Robert Newberry, a safety officer at Clemson University, technicians at clinical laboratories face fewer laboratory-imposed restrictions on their behavior and thus are often in the best position to divert a select agent for weapons use. *Id.* (further noting that the exemption was “sheer lunacy”).

²³³The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594, § 201(g)(1)(A)-(B) (later codified at 42 U.S.C. § 262a(g)(1)(A)-(B)). Reaction to the agent disposal provision was also mixed. As Scott Weaver, a virologist at the University of Texas Medical Branch in Galveston, noted, “requiring these labs to destroy samples containing select agents within 7 days could hamper future scientific and criminal investigations.” Malakoff, *Security Rules Leave Labs Wanting More Guidance*, *supra* note 232 (further underlining that “our future ability to identify the source of a terrorist introduction [depends] on having collections of reference agents”).

²³⁴The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594, § 201(g)(2) (later codified at 42 U.S.C. § 262a(g)(2)).

²³⁵*Id.* at § 201(g)(3)-(4) (later codified at 42 U.S.C. § 262a(g)(3)-(4)).

The PHSBPRA exempted from mandatory disclosure under the Freedom of Information Act (“FOIA”) site-specific or identifying information submitted pursuant to the CDC regulations concerning registered individuals or entities, agents, or laboratory security measures, and further exempted any information contained in the CDC national database.²³⁶ This exemption did not extend, however, to disclosure of information to Congress, or disclosure mandated pursuant to any federal law besides FOIA.²³⁷

b.

The PHSBPRA significantly increased civil penalties for violators: individuals caught possessing or transferring agents without registration and approval could be fined up to \$250,000, and entities up to \$500,000.²³⁸ Similarly, a violator could be subject to up to 5 years of jail time for noncompliance.²³⁹

c.

In distinct contrast to the AEDPA, the PHSBPRA mandated that the CDC coordinate its regulations with USDA regulations governing the use of select agents in the development of vaccines and other products for the treatment of domestic animals.²⁴⁰ The USDA regulations, which did not exist prior to the PHSBPRA’s passage and whose establishment was thus required by the legislation, pertained solely to agents with the potential to affect animal and plant health and were intended to guard against the illicit use of agents in agricultural terrorism attacks.²⁴¹ The USDA regulations were eventually codified at 7 C.F.R. § 331 and 9 C.F.R. § 121, respectively.²⁴² Coordination between the CDC and USDA was designed to ensure a minimization of conflict and to avoid a duplication of administrative burdens for registered entities.²⁴³

²³⁶ *Id.* at § 201(h)(1) (later codified at 42 U.S.C. § 262a(h)(1)).

²³⁷ *Id.* at § 201(h)(5)(A)-(B) (later codified at 42 U.S.C. § 262a(h)(5)(A)-(B)).

²³⁸ *Id.* at § 201(i)(1) (later codified at 42 U.S.C. § 262a(i)(1)).

²³⁹ *See Id.* at § 231(b)(1), § 231(c)(1) (later codified at 18 U.S.C. § 175(b)).

²⁴⁰ *Id.* at § 221(a)(1). The USDA program was run through the Animal and Plant Health Inspection Service (APHIS). *HHS, USDA Establish New Regulations for Use of Select Biological Agents*, U.S. NEWSWIRE, December 10, 2002.

²⁴¹ Agricultural Bioterrorism Protection Act of 2002: Possession, Use, and Transfer of Biological Agents and Toxins, 67 Fed. Reg. 76908 (December 13, 2002).

²⁴² *Id.*

²⁴³ The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594, §

It was also intended, however, to ensure the appropriate availability of agents for legitimate biomedical, agricultural, and veterinary research.²⁴⁴ The PHSBPRA envisioned a single registration process for entities possessing or transferring an “overlap agent,” defined as “any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa) or toxin [posing] a risk to both human and animal health” and subsequently listed at 42 C.F.R. § 73 and 9 C.F.R. § 121.²⁴⁵ Each agency was required to notify the other in the event of an overlap application, an acceptance of registration, or a revocation or denial of access.²⁴⁶ Inspection and other verification responsibilities were to be shared among the two agencies.²⁴⁷ Both the USDA and CDC were to issue joint regulations no later than 18 months after enactment.²⁴⁸

Possessors were given 90 days to comply with the legislation and the CDC’s new regulatory mandate.²⁴⁹ To expedite compliance, the CDC was required to publish an interim final rule no later than 180 days after enactment of the PHSBPRA, and to submit a compliance report to Congress within the year.²⁵⁰ The CDC was also required to report to Congress on the actions and future plans of the CDC with regard to its select agent list, as well as the impact of its regulation on legitimate scientific research.²⁵¹ In order to ensure improved implementation of the new rule vis-à-vis the 1997 regulation, the PHSBPRA appropriated an additional \$3.6 million to the CDC for the 2002 fiscal year.²⁵² The CDC was also authorized to fund 21 staff members under the Select Agent Program – up from 9 in the 2001 fiscal year

221(b)(1)-(2).

²⁴⁴ *Id.* at § 221(b)(3).

²⁴⁵ Agricultural Bioterrorism Protection Act of 2002: Possession, Use, and Transfer of Biological Agents and Toxins, 67 Fed. Reg. 76908, *supra* note 241, at 76932.

²⁴⁶ *Id.* at § 221(c)(2).

²⁴⁷ *Id.* at § 221(c)(4).

²⁴⁸ *Id.* at § 221(d).

²⁴⁹ *Id.* at § 202(a); *see also* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Possession, Use, and Transfer of Select Agents and Toxins, Public Meeting, Centers for Disease Control and Prevention, PowerPoint Presentation, December 16, 2002, available at <http://www.cdc.gov/od/sap/cdc-05a.htm>. The CDC published a notice in the Federal Register on August 6, 2002, requiring all facilities in possession of select agents to notify the CDC by September 10. Notice of OMB Approval of Data Collection, 67 Fed. Reg. 51058 (August 6, 2002); *Openness vs. Security in Science Research: Hearing Before the House Comm. on Science*, 107th Cong. (2002) (statement of John H. Marburger, Director, Office of Science and Technology Policy). The CDC further sent a notification form to over 200,000 institutions for this purpose, requesting a response regardless of actual agent possession. *Id.* By mid-October, the CDC had processed over 100,000 responses, with only a small percentage declaring possession. *Id.* The CDC expected approximately 1,800 facilities to eventually report possession. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Possession, Use, and Transfer of Select Agents and Toxins, Public Meeting, Centers for Disease Control and Prevention, PowerPoint Presentation, December 16, 2002, available at <http://www.cdc.gov/od/sap/cdc-05a.htm>.

²⁵⁰ The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594, §§ 201(n) and §202(b)(1).

²⁵¹ *Id.* at § 201(b)(2)-(4).

²⁵² UNITED STATES GENERAL ACCOUNTING OFFICE, HOMELAND SECURITY: CDC’S OVERSIGHT OF THE SELECT AGENT PROGRAM, GAO-03-315R, *supra* note 199, at 3.

– primarily because program members expected their duties to increase tenfold given the large number of entities possessing, rather than transferring, select agents.²⁵³

On August 23, 2002, the CDC published a notice of intent to issue regulations, further specifying in its notice those agents being considered for inclusion on both the select agent and overlap lists.²⁵⁴ The notice invited public comments on the CDC’s proposed list, which had been developed with input from an interagency working group composed of representatives from DHHS, NIH, the FDA, the Departments of the Army, Navy, and Air Force, the USDA, the EPA, the Agency for Toxic Substances and Disease Registry, OSHA, the National Institute of Occupational Safety and Health, the Department of Transportation, the Department of Commerce, the Department of Energy, the FBI, the CIA, DOJ, the DIA, and the U.S. Postal Service.²⁵⁵ As the CDC noted, 18 of the 36 agents included on its original select agent list were, in fact, “overlap agents” monitored by both the USDA and CDC.²⁵⁶ A majority of the CDC’s changes thus reflected the eventual merge of these agents into a combined USDA/CDC list of regulated viruses and bacteria.²⁵⁷ Other alterations included edits in agent nomenclature and several additions/removals vis-à-vis the original list.²⁵⁸ For example, the CDC recommended removal of yellow fever from the category of regulated viruses, while adding monkeypox and Hepatitis B.²⁵⁹ Overall, the CDC changes would increase the number of regulated agents from 36 to 39.

As the CDC began drafting its interim final rule, it found itself once again at the receiving end of governmental criticism. On November 22, 2002, the U.S. General Accounting Office (“GAO”) released a performance review of the CDC Select Agent Program that highlighted major program defects and suggested several areas for potential improvement.²⁶⁰ More specifically, the GAO report found “significant management weak-

²⁵³*Id.* at 3-4.

²⁵⁴Interstate Shipment of Etiologic Agents, Select Agents, 67 Fed. Reg. 54605 (August 23, 2002) (revising the list of select agents and associated genetic elements). The CDC and USDA published a list of “overlap agents” the same day. The USDA issued its proposed list of biological agents and toxins on August 12, 2002. Agricultural Bioterrorism Protection Act of 2002; Listing of Biological Agents and Toxins and Requirements and Procedures for Notification of Possession, 67 Fed. Reg. 52383 (August 12, 2002).

²⁵⁵Interstate Shipment of Etiologic Agents, Select Agents, 67 Fed. Reg. 54605, *supra* note 254, at 54606.

²⁵⁶*Id.*

²⁵⁷*Id.*

²⁵⁸*Id.* at 54606-54607.

²⁵⁹*Id.* at 54606.

²⁶⁰UNITED STATES GENERAL ACCOUNTING OFFICE, HOMELAND SECURITY: CDC’S OVERSIGHT OF THE SELECT AGENT PROGRAM, GAO-03-315R, *supra* note 199.

nesses” in the CDC’s facility registration and transfer monitoring processes, noting that the CDC needed to establish proper internal controls in accordance with OMB Circular A-123²⁶¹ and institute changes in the inspection and approval of registering facilities, the accuracy of its databases, and its oversight structure.²⁶² The GAO distributed copies of its report to the Senate Committees on Appropriations, Governmental Affairs, and Health, Education, Labor and Pensions, as well as the House Committees on Appropriations, Energy and Commerce, and Government Reform.²⁶³ In response to the GAO criticism, DHHS Secretary Thompson promised to undertake corrective action, and noted that, as the CDC instituted its new duties under the PHSBPRA, some improvements were already underway.²⁶⁴ In fact, on December 6 – two weeks after the publication of the GAO report – the CDC issued revised guidelines in the *Morbidity and Mortality Weekly Report*.²⁶⁵ The revised guidelines, entitled “Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents,” amended the 1999 version of the CDC’s BMBL to include measures related to risk assessment, information technology systems, personnel policies, record keeping, emergency response, and incident reports.²⁶⁶ Among other recommendations, the guidelines suggested that labs should maintain up-to-date inventories, develop transfer and shipment procedures, implement an emergency response plan, and notify CDC or the USDA immediately in the event of an agent loss or release.²⁶⁷

Pursuant to the PHSBPRA’s mandate, the CDC published its interim final rule on December 13, 2002.²⁶⁸ The rule, designed to “provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States,” established detailed requirements regarding the possession and use of select agents.²⁶⁹ Found at 42 CFR 73, the new rule superseded 42 CFR 72.6, which

²⁶¹Office of Management and Budget, OMB Circular A-123, *Management Accountability and Control*, (1995). *Id.* As the GAO noted, this document provides the specific requirements for assessing and reporting on controls. *Id.* at n.4.

²⁶²*Id.* at 5.

²⁶³*Id.* at 6.

²⁶⁴*Id.* at 5; see also Robert Roos, *CDC Expands Security Guidelines for Labs Handling Dangerous Pathogens*, December 6, 2002, available at <http://www.cidrap.umn.edu/cidrap/content/bt/bioprep/news/selagents.html>.

²⁶⁵*Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents*, 51 MORBIDITY & MORTALITY WEEKLY RPT. RR-19 (2002); see also Robert Roos, *CDC Expands Security Guidelines for Labs Handling Dangerous Pathogens*, December 6, 2002, available at <http://www.cidrap.umn.edu/cidrap/content/bt/bioprep/news/selagents.html>.

²⁶⁶For information concerning the CDC’s BMBL, see *supra* note 36. While the previous version of the guidelines primarily addressed physical security measures to prevent theft of select agents, the new version broadened the CDC’s recommendations to include risk assessment, information technology systems, personnel policies, record-keeping, emergency response, and reporting of incidents, as well as access control. Robert Roos, *CDC Expands Security Guidelines for Labs Handling Dangerous Pathogens*, December 6, 2002, available at <http://www.cidrap.umn.edu/cidrap/content/bt/bioprep/news/selagents.html>.

²⁶⁷See *id.*

²⁶⁸Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76886 (December 13, 2002). The USDA published its interim rule on the same day. *HHS, USDA Establish New Regulations for Use of Select Biological Agents*, *supra* note 240.

²⁶⁹Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76886, *supra* note 268.

was instituted by the CDC in its 1997 rulemaking.²⁷⁰ The rule applied primarily to academic institutions and biomedical centers, the pharmaceutical industry, federal, state, and local laboratories, and research facilities, and served to inform the scientific community at large of its new duties under the PHSBPRA.²⁷¹ The changes to the CDC's oversight duties were significant:

a.

The CDC's interim final rule expanded the number of regulated agents from 36 to 39.²⁷² The 39 regulated agents included 20 HHS select agents and 19 "overlap" agents.²⁷³ Of the 20 HHS select agents, 9 were viruses, 3 bacteria, 1 fungi, and 7 toxins.²⁷⁴ The "overlap" agent list was composed of 4 viruses, 9 bacteria, 1 fungi, and 5 toxins.²⁷⁵ In contrast to the 1997 CDC regulation, both lists excluded agents or toxins in their naturally occurring environments from oversight, provided the agent was not intentionally collected, cultivated, or otherwise extracted from its natural source.²⁷⁶ The lists also allowed exemptions for vaccine or otherwise "attenuated" strains upon a determination by HHS or the USDA, respectively, that the agent strain did not pose a severe threat to the public health.²⁷⁷

b.

Pursuant to the PHSBPRA's mandate, the CDC interim final rule introduced registration requirements for possessors of select agents.²⁷⁸ As the CDC explanatory note stated, an entity could not possess, use,

²⁷⁰*Id.*

²⁷¹*Id.* at 76895.

²⁷²This number was reached by comparing the agents listed in Additional Requirements for Facilities Transferring or Receiving Select Agents, 61 Fed. Reg. 55190, *supra* note 80, at 55199-55200 (codified at Appendix A of 42 C.F.R. § 72) with the agents listed in Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76886, *supra* note 268, at 76898-76899 (codified at 42 C.F.R. § 73.4 and 42 C.F.R. § 73.5).

²⁷³*See id.*, codified at 42 C.F.R. § 73.4 and 42 C.F.R. § 73.5.

²⁷⁴*Id.* at 76898, codified at 42 C.F.R. § 73.4(a)-(e).

²⁷⁵*Id.* at 76898-76899, codified at 42 C.F.R. § 73.5(a)-(e).

²⁷⁶*Id.*, codified at 42 C.F.R. § 73.4(f)(1) and 42 C.F.R. § 73.5(f)(1).

²⁷⁷*Id.*, codified at 42 C.F.R. § 73.4(f)(5) and 42 C.F.R. § 73.4(f)(5).

²⁷⁸*See generally id.* at 76900, codified at 42 C.F.R. § 73.7(a).

transfer, or receive any select agent – even from a laboratory outside of the United States – unless the entity registered with the CDC.²⁷⁹ Registration involved receiving an application number from the CDC and submitting detailed identification information, as articulated in the PHSBPRA, to the CDC and Attorney General.²⁸⁰ An entity’s registration was only valid for the specific select agents listed in its application, as well as for the activities and location reported to the CDC, although an amendment process was available.²⁸¹ A certificate of registration was deemed valid for only three years, and to obtain a new certificate, an entity was required to submit a new application.²⁸² The CDC retained broad oversight and revocation powers, and could terminate an entity’s registration for failure to comply with any of the interim final rule’s provisions.²⁸³ Upon termination of an entity’s registered status, the entity was required to destroy or dispose of all select agent cultures according to prescribed HHS standards.²⁸⁴

c.

In direct contrast to the 1997 rule, the new interim rule provided detailed measures for laboratory security. An entity could not provide employee access to select agents unless each employee had been approved by the CDC as capable of safely handling the agent at the appropriate Biosafety level and had been subject to a risk assessment by the Attorney General.²⁸⁵ Once granted, CDC approval to handle select agents was

²⁷⁹*Id.* at 76886.

²⁸⁰*Id.* at 76900, codified at 42 C.F.R. § 73.7(b)(1)-(2). The CDC rule lists an entity’s “registering information” as 1) the entity’s name, address, contact numbers, and identification number as assigned by the Attorney General 2) the name, source, and characterization of the select agent or toxin included in the entity’s registration, as well as the quantity held at the time of registration, 3) the location, including building and room number, where each agent or toxin will be stored at the entity, complete with applicable floor plans, 4) information addressing safety, security, emergency response plans, and training at the entity, 5) the name, position, and identification information for the entity’s responsible official, 6) a list of all individuals needing access to the agent or toxin, and 7) a certification by the responsible official attesting to the application’s honesty and accuracy. *Id.*, codified at 42 C.F.R. § 73.7(b)(2)(i)-(vii). The CDC also reserved the right to consider “any other information necessary for the determination.” *Id.* at 42 C.F.R. § 73.7(b)(2)(viii).

²⁸¹*Id.*, codified at 42 C.F.R. § 73.7(d)-(e).

²⁸²*Id.*, codified at 42 C.F.R. § 73.7(g).

²⁸³*Id.*, codified at 42 C.F.R. § 73.7(g)(1)-(2).

²⁸⁴*Id.*, codified at 42 C.F.R. § 73.7(g)(2) and § 73.7(h).

²⁸⁵*Id.* at 76901, codified at 42 C.F.R. § 73.8(a). For a discussion of the adoption of the background screening requirement, see H.R. REP. NO. 107-481, 120-121 (2002), as well as The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594, § 201(e)(1). The CDC rule stated that to obtain a security risk assessment, a registering entity must submit to the Attorney General its registration application, as well as any other information requested by the Attorney General for the entity, its responsible official, any individual controlling the entity, or individuals working with the agent. Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76886, *supra* note 268, at 76901, codified at 42 C.F.R. § 73.8(c)-(d). The Attorney General later delegated its risk assessment authority to the FBI. Possession, Use, and Transfer of Select Agents and Toxins, 68 Fed. Reg. 62245 (Nov. 3, 2003). The Criminal Justice Information Services Division (CJIS) is the FBI component responsible for implementing the assessment program. *Id.*

effective for five years, although the CDC could grant shorter terms when necessary or expedient.²⁸⁶ As the PHSBPRA mandated, the CDC included in its interim rule procedures for expedited review.²⁸⁷ As in its earlier 1997 rule, each registering entity was required to designate a responsible official with the authority to ensure compliance with the CDC regulation.²⁸⁸ Registering entities were required to develop and implement a safety plan, a security plan, and an emergency response plan, and the entity's responsible official was to conduct regular inspections to guarantee their effectiveness.²⁸⁹ The security plan, in particular, was to be reviewed at least annually.²⁹⁰ Entities were directed to ensure that only approved employees received unescorted access to areas containing select agents and toxins, and were to require the inspection of all packages entering and exiting the area.²⁹¹ Each facility was required to establish a protocol for intra-entity transfers, as well as develop procedures for the rapid reporting of an agent theft, loss, or release, or other inventory compromise.²⁹² Similarly, each facility was to provide regular and proper training for all employ-

²⁸⁶Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76886, *supra* note 268, at 76901, codified at 42 C.F.R. § 73.8(f).

²⁸⁷*Id.*, codified at 42 C.F.R. § 73.8(g).

²⁸⁸*Id.*, codified at 42 C.F.R. § 73.9(a). According to the CDC rule, the facility's responsible official may identify one or more individuals to serve as "alternate responsible officials" when the responsible official is unavailable to complete his duties. *Id.* Under the rule, the responsible official is required to ensure compliance with all aspects of the CDC's regulation, including (1) developing and implementing safety, security, and emergency response plans, (2) allowing only approved individuals to have access to select agents and toxins, (3) providing appropriate training, safety, security, and emergency response, (4) transferring select agents and toxins, (5) providing timely notice of agent theft, loss, or release, (6) maintaining detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins, and (7) reporting the identification of a select agent or toxin as a result of diagnostic, verification, or proficiency testing. *Id.* at 42 C.F.R. § 73.9(c)(1)-(7). According to the CDC rule, the facility's responsible official may identify one or more individuals to serve as "alternate responsible officials" when the responsible official is unavailable to complete his duties. *Id.*, codified at § 73.9(a).

²⁸⁹*Id.* at 76901-76903, codified at 42 C.F.R. § 73.10(a) (safety plan), 42 C.F.R. § 73.11(a) (security plan), 42 C.F.R. § 73.12 (emergency response plan), 42 C.F.R. § 73.10(b) (inspections related to efficacy of safety plan). According to the rule, the facility's safety plan was to be based on the CDC BMBL guidelines. *Id.* at 76901-76902, codified at 42 C.F.R. § 73.10(a)(1)-(2). The facility's security plan was to (1) describe inventory control procedures, minimal education and experience criteria for individuals with agent access, and physical security measures, (2) contain provisions for routine cleaning, maintenance, and repairs, provisions for training personnel in security procedures, provisions for securing the area where the agent is stored, and protocols for altering locks and staff access in the event of personnel change, (3) describe procedures for loss or compromise of keys and passwords, (4) contain procedures for reporting suspicious persons or activities, loss, theft, or release of listed agents or toxins, or alteration of inventory records, (5) contain provisions for the control of access to containers where listed agents and toxins are stored, (6) contain provisions for ensuring that all individuals with agent access understand security requirements and are trained to follow established procedures, (7) contain procedures for reporting and removing unauthorized persons, and (8) establish specific procedures for securing the area where agents are stored or researched when individuals unapproved for access under 42 C.F.R. § 73.8, *supra* note 285, are present. *Id.* at 76902, codified at 42 C.F.R. § 73.11(b)(1)-(8). A facility's emergency response plan was required to apply to such events as bomb threats, severe weather, earthquakes, power outages, and other natural disasters. *Id.* at 76903, codified at 42 C.F.R. § 73.12(b). The plan was to further address (1) the hazards associated with the use of select agents or toxins, (2) any hazard associated with response actions that could lead to the agent's spread, (3) planning and coordination with outside parties, (4) personnel roles, lines of authority, and training and communications, (5) emergency recognition and prevention, (6) safe distances and places of refuge, (7) site security and control, (8) evacuation routes and procedures, (9) decontamination, (10) emergency medical treatment and first aid, (11) emergency alerting and response procedures, (12) critique of response and follow-up, (13) personal protective and emergency equipment, and (14) special procedures to address the hazards of specific agents. *Id.*, codified at 42 C.F.R. § 73.12(c)(1)-(14).

²⁹⁰*Id.*, codified at 42 C.F.R. § 73.11(c).

²⁹¹*Id.*, codified at 42 C.F.R. § 73.11(d)(1)-(4).

²⁹²*Id.*, codified at 42 C.F.R. § 73.11(d)(5) (intra-entity transfers) and 42 C.F.R. § 73.11(d)(7)(i)-(v) (reporting procedures).

ees or other individuals handling select agents.²⁹³ If an employee had been working with select agents for a lengthy period of time prior to the regulation, the responsible official could certify in writing that the employee possessed appropriate knowledge and skills in lieu of attendance at training sessions.²⁹⁴ Registered entities were ordered to separate areas where select agents and toxins would be stored or used from public areas of the building.²⁹⁵ Finally – and perhaps most controversially – prior HHS approval was required for all experiments involving recombinant DNA that might result in a higher level of agent toxicity or drug resistance.²⁹⁶

d.

Transfer requirements remained largely the same under the new interim rule, with one significant difference: prior approval had to be received from either the CDC or USDA (if the agent at issue was an “overlap” agent) before undertaking any agent transfer.²⁹⁷ The regulation additionally required a recipient facility to notify the HHS Secretary if the select agent was not received within 48 hours of the expected delivery time, or if the package containing the agent was leaking or damaged.²⁹⁸ A recipient facility was also required to report an agent’s destruction or use to the HHS Secretary within 5 days of such action.²⁹⁹

²⁹³ *Id.* at 76903, codified at 42 C.F.R. § 73.14(a)-(c).

²⁹⁴ *Id.*, codified at 42 C.F.R. § 73.14(d).

²⁹⁵ *Id.* at 76902, codified at 42 C.F.R. § 73.11(e).

²⁹⁶ *Id.*, codified at 42 C.F.R. § 73.10(c)(1)-(2). Government-funded scientists were already subject to such a restriction under National Institutes of Health (“NIH”) guidelines. David Malakoff, *New U.S. Rules Set the Stage for Tighter Security*, 298 SCIENCE 2304 (Dec. 20, 2002). While some scientists believed expanding the NIH guidelines to all researchers under the CDC rule was a good idea, *see id.* (biochemist Richard Ebright of the Howard Hughes Medical Institute, noting that the review list should include experiments that could lead to less effective vaccines or improve methods of producing bioweapons and further suggesting that “it’s common sense that such work get stricter scrutiny”), others felt that the CDC was entering dangerous territory. According to Ronald Atlas, President of the American Society for Microbiology, the CDC regulation raised several concerns. First, because the CDC’s oversight was codified via regulation rather than guideline, changes in the oversight process would be much more difficult to affect. Atlas wasn’t sure that “the government should start proscribing experiments... and locking rules into regulations,” and noted that guidelines are more flexible and can be easily adjusted to changing circumstances. *Id.* Second, Atlas and other researchers highlighted that the regulation was silent as to who at the CDC would review sensitive experiments. *Id.* While the NIH conducted most oversight reviews in public, researchers noted, secrecy could be deemed important in an area with significant implications for national security. *Id.* If so, one anonymous scientist pointed out, “there is going to be an issue around transparency.” *Id.*

²⁹⁷ Possession, Use, and Transfer of Select Agents and Toxins, 67 Fed. Reg. 76886, *supra* note 268, at 76903, codified at 42 C.F.R. § 73.14(d).

²⁹⁸ *Id.*, codified at 42 C.F.R. § 73.14(g).

²⁹⁹ *Id.*, codified at 42 C.F.R. § 73.14(h).

e.

The interim rule imposed, for the first time in regulatory history, significant inventory controls on registering facilities. According to the rule, a facility's responsible official was required to maintain an up-to-date, accurate list of individuals approved for agent access, a current inventory of each select agent held in an on-site repository or in the facility's possession, a record of every agent access by an employee, and a record of all inspections, safety, security, and emergency response plans, trainings, transfer documents, and incident reports.³⁰⁰ Facilities were required to retain records for a minimum of three years.³⁰¹

f.

The interim rule afforded greater authority to the CDC to conduct inspections. In fact, the CDC was given blanket inspection control, and could enter a facility unannounced with or without cause.³⁰²

g.

³⁰⁰ *Id.* at 76903-76904, codified at 42 C.F.R. § 73.15(a)-(i). More specifically, inventory records were required to include (1) the agent's name, characteristics, and source data, (2) the quantity of agent held on the date of the first inventory, (3) the quantity of agent acquired, the source, and the date of acquisition, (4) the quantity, volume, or mass destroyed or disposed of, and the date of each such action, (5) the quantity used and the dates of such use, (6) the quantity transferred, the date of transfer, and the individual to whom it was transferred, for both inter- and intra-entity transfers (7) the current quantity of agent or toxin held, (8) any agent or toxin lost, stolen, or otherwise unaccounted for, and (9) a written explanation of any discrepancies. *Id.* at 76903, codified at 42 C.F.R. § 73.15(b)(1)-(9). For select agents or toxins accessed, the facility was required to retain records of (1) the name of each individual who accessed the select agent, (2) the select agent or toxin used, (3) the date when the select agent or toxin was removed, if removed from long-term storage, (4) for toxins, the quantity removed, (5) the date the select agent or toxin was returned to long-term storage, and (6) for toxins, the quantity returned. *Id.*, codified at 42 C.F.R. § 73.15(c)(1)(i)-(vi). For access to the storage area for select agents or toxins, the facility was required to retain records of (1) the name of each individual who accessed the area, (2) the date and time the individual entered the area, (3) the date and time the individual left the area, and (4) for individuals unapproved for access under 42 C.F.R. § 73.8, *supra* note 285, the individual approved under 42 C.F.R. § 73.8 who accompanied the individual into the area. *Id.*, codified at 42 C.F.R. § 73.15(c)(2)(i)-(iv).

³⁰¹ *Id.*, codified at 42 C.F.R. § 73.15(j).

³⁰² *Id.* at 76904, codified at 42 C.F.R. § 73.16; *see also* Malakoff, *New U.S. Rules Set the Stage for Tighter Security*, *supra* note 296.

As mandated by the PHSBPRA, a registering entity was required to notify the CDC and federal, state, and local law enforcement authorities in the event of an agent theft, loss, or release, regardless of whether the agent is eventually recovered.³⁰³

h.

The interim rule allowed registering entities to obtain review of decisions denying or revoking a certificate of registration or denying or revoking approval to handle an agent, provided that such review was requested within 30 days of the initial agency action.³⁰⁴ Where the agency decision was rendered by the Attorney General pursuant to its risk assessment authority, the Attorney General was given responsibility to conduct the review, with notification of the decision forwarded to the DHHS Secretary.³⁰⁵ The DHHS Secretary delegated its authority to conduct compliance inspections and impose civil monetary penalties to the Inspector General of DHHS, and further delegated the ability to conduct hearings and render decisions with respect to monetary penalties to the DHHS Departmental Appeals Board (“DAB”).³⁰⁶

The interim final rule became effective on February 7, 2003.³⁰⁷ After publication of the rule, the CDC requested written comments, which had to be received prior to February 11, 2003 in order to be considered by the CDC in its drafting of the final rule.³⁰⁸ The CDC held a public forum on December 16, 2002 on the Possession, Use, and Transfer of Select Agents and Toxins, and invited regulated entities and other interested parties to orally comment on the interim rule.³⁰⁹ At the forum, representatives from the Select

³⁰³*Id.*, codified at 42 C.F.R. § 73.17(a)-(b) (agent loss or theft) and 42 C.F.R. § 73.17(d) (agent release). When reporting a theft or loss, an entity must provide (1) the name of the select agent or toxin and related identifying information, (2) an estimate of the quantity lost or stolen, (3) an estimate of the time during which the theft or loss occurred, (4) the location, including the building or room number, from which the theft or loss occurred. *Id.*, codified at 42 C.F.R. § 73.17(c)(1)-(4). When reporting an agent release, an entity must provide (1) the name of the select agent or toxin and related identifying information, (2) an estimate of the quantity released, (3) the time and duration of the release, (4) the environment into which the release occurred, (5) the location from which the release occurred, (6) the number of individuals potentially exposed at the facility, (7) actions taken to respond to the release, and (8) hazards posed by the release. *Id.*, codified at 42 C.F.R. § 73.17(e)(1)-(8).

³⁰⁴*Id.*, codified at 42 C.F.R. § 73.18.

³⁰⁵*Id.*

³⁰⁶*Id.*, codified at 42 C.F.R. § 73.19(a) (Inspector General) and 42 C.F.R. § 73.9(b) (DAB).

³⁰⁷*Id.* at 76886.

³⁰⁸*Id.*

³⁰⁹HHS, *USDA Establish New Regulations for Use of Select Biological Agents*, *supra* note 240; *see also* U.S. Department of Agriculture and U.S. Department of Health and Human Services, Public Meeting on the Interim Final Rule for Select Agents, December 16, 2002, available at <http://www.cdc.gov/od/sap/>.

Agent Program explained the registration and risk assessment deadlines instituted by the interim final rule, and noted that all entities possessing, using, or transferring select agents were required to be in full compliance by November 12, 2003.³¹⁰ Despite the imposition of a large number of new requirements, the CDC stated that it did not believe the rule would pose a significant burden on regulated entities, as the agency expected that a great majority were already in compliance.³¹¹ Nevertheless, many facilities possessing select agents quickly complained that the CDC registration timeline was not realistic and would in fact disrupt laboratory work.³¹² Moreover, a number of entities complained that the CDC's rule, particularly the physical security provision, was too stringent for laboratories handling lower-risk select agents at Biosafety Level 2 or 3.³¹³ Because the regulations could force regulated entities to build separate facilities in order to comply with the safety and security requirements – an expensive prospect – commenters argued that the rule would greatly impede legitimate research.³¹⁴

Written comments submitted over the next two months mirrored the concerns raised at the CDC public forum. According to a majority of the over 100 comments, many elements of the CDC's rule were “vague, confusing, and possibly counterproductive.”³¹⁵ As the American Society for Microbiology noted, the rules “require[d] a large number of activities in a short period,” resulting in start-up compliance costs of up to

³¹⁰*Id.* (statements of Dr. Stephen Ostroff and Mr. Sparks).

³¹¹*Id.*

³¹²*Id.* (statement of Ronald Atlas, President of the American Society of Microbiology) (noting that “although the regulation includes a phase-in or transition period for a number of requirements, it's not clear to us that we're really going to be able to meet all of the requirements in time to keep the laboratories functioning”); *see also id.* (statement of Michael Durham, Director of Occupational and Environmental Safety, Louisiana State University) (stating that the “new regulations issued go too far in too short a period of time” and recommending that “the timetable be adjusted so that we'll be able to achieve it”). The CDC's proposed timeline can be found in Appendix 2 of this paper; *see also* David Malakoff, *Security Rules Leave Labs Wanting More Guidance*, *supra* note 232 (quoting the American Society of Microbiology, who stated that the rules “require a large number of activities in a short period”).

³¹³U.S. Department of Agriculture and U.S. Department of Health and Human Services, Public Meeting on the Interim Final Rule for Select Agents, December 16, 2002, available at <http://www.cdc.gov/od/sap/> (statement of Michael Durham, Director of Occupational and Environmental Safety, Louisiana State University) (asserting that

“the regulations be modified to reflect the actual gravity of the various agents and toxins and the likelihood of harm occurring from each”); *see id.* (statement of Emmett Berkeley, Director of the Office of Laboratory Safety, Howard Hughes Medical Institute) (stating that the “security and the security and emergency response provisions are too stringent for select agents and toxins not mandated for control within maximum containment facilities”).

³¹⁴*Id.* (statement of Michael Durham, Director of Occupational and Environmental Safety, Louisiana State University) (noting that the new security measures “were probably going to limit the number of locations and institutions where this research can be performed,” in turn “immediately reducing the creativity and research that will impede the accumulation of knowledge”); *see also* Diana Jean Schemo, *Sept. 11 Strikes At Labs' Doors*, N.Y. Times, August 13, 2002, at F1 (noting that “many institutions are planning to build new high-security laboratories – bucking a trend toward open spaces that encourage scientists to share knowledge and materials – or throw up new walls in existing labs”).

³¹⁵David Malakoff, *Security Rules Leave Labs Wanting More Guidance*, *supra* note 232, at 1175. Full-text versions of the submitted comments can be accessed at www.cdc.gov/od/sap/docket.htm.

\$700,000 per lab and forcing facilities to focus on adherence to the rule rather than research.³¹⁶ The Society further complained that the provisions requiring that facilities notify the authorities even if they have no select agents were unnecessarily burdensome.³¹⁷ Lab administrators appeared particularly concerned about the mandatory employee background checks. CDC officials estimated that as many as 20,000 researchers at nearly 1000 laboratories would have to be screened pursuant to the rule before being authorized to access select agents, but highlighted that the regulation avoided a blanket ban on foreign scientists and gave the Secretary some discretion over potential waivers.³¹⁸ Nevertheless, many labs – especially academic institutions – felt restrictions on access violated their scientific mission. For example, in reviewing the CDC rule, a faculty committee at the Massachusetts Institute of Technology argued that security clearances for students and limitations on agent access were “not consistent with MIT principles” and recommended that MIT consider refusing campus work on select agents.³¹⁹ While no other lab to date has taken MIT’s position, several have insisted that the CDC reevaluate its position concerning unauthorized access, particularly because researchers working on a wide range of experiments often share space and equipment.³²⁰ One recommendation, put forth by the Howard Hughes Medical Institute of Chevy Chase, MD, would have allowed laboratories to develop systems to limit access to select agents, for instance by storing agents in locked freezers, without barring all unscreened workers from the area where select agent research was undertaken.³²¹ Isolating materials rather than researchers would thus limit the number of background checks needed while decreasing the cost of compliance for both the government and the labs.³²² The provision that received the greatest criticism was the CDC’s requirement that scientists receive prior approval for genetic experiments that could increase agent toxicity or drug resistance. Although federally-funded scientists were already subject to a similar

³¹⁶*Id.*; see also David Malakoff, *New U.S. Rules Set the Stage for Tighter Security*, *supra* note 296.

³¹⁷Diana Jean Schemo, *Sept. 11 Strikes At Labs’ Doors*, *supra* note 314, at F1. Barry Kellman further underlined this criticism, noting that “every laboratory must scour through its freezers and other storage sites for such items lest they materialize unexpectedly” and that for many laboratories, “collections of pathogens are improperly labeled, complicating the task of conducting a complete inventory.” Kellman, *Regulation of Biological Research in the Terrorism Era*, *supra* note 66, at 163. In fact, Kellman argued that prior to the regulation, only a conscious decision to transfer a select agent invoked a regulatory obligation, while the new obligation applied to every agency regardless of an entity’s choice in structuring its actions. *Id.*

³¹⁸David Malakoff, *Security Rules Leave Labs Wanting More Guidance*, *supra* note 232, at 1175; see also 42 U.S.C. §262(e).

³¹⁹Diana Jean Schemo, *Sept. 11 Strikes At Labs’ Doors*, *supra* note 314, at F1. In hearings before the House Subcommittee on Technology, Terrorism, and Government Reform, Ronald Atlas, President of the American Society for Microbiology, argued that this reaction was precisely what government regulation should have sought to avoid. According to Atlas, “we need the researchers to find the vaccines and the pharmaceuticals. If we... do not have legitimate researchers doing research on anthrax, we will not have the drugs and the vaccines in the future to combat any bioterrorist attack. Much of that research goes on at our universities, as well as in the federal labs and other industrial laboratories. That’s absolutely critical to the welfare of the nation.” *Germes, Toxins, and Terror, The New Threat to America: Hearing Before the Subcomm. on Technology, Terrorism, and Government Reform of the Senate Comm. on the Judiciary*, 107th Cong. (2001) (statement of Dr. Ronald Atlas, President, American Society for Microbiology) (responding to questions posed by Sen. Feinstein).

³²⁰David Malakoff, *Security Rules Leave Labs Wanting More Guidance*, *supra* note 232, at 1175.

³²¹*Id.*

³²²*Id.*

restriction under National Institutes of Health guidelines, many in the scientific community believed that converting flexible guidelines to an inflexible rule would hinder scientific advances and detrimentally effect public health in the long run.³²³

As with the CDC's 1997 regulation, comments expressed doubts that the new CDC measures – designed precisely to close gaps that allowed unauthorized access to agents – would actually prevent access to biological materials by dedicated terrorists. According to the commenters, many of the cultures “going under lock and key at great expense,” such as Ebola or plague, were in fact freely available in countries with natural outbreaks.³²⁴ Moreover, most of the 1500 culture collections around the world could provide select agents to researchers with very few restrictions or controls.³²⁵ Thus, in the absence of an international agreement criminalizing bioterrorism or a harmonization of transfer and shipment requirements across borders, the CDC regulation, it was argued, was likely to have little impact.³²⁶ In the words of one critic, “it doesn't do us a lot of good to tighten our national regulations over the exchange or possession of agents if one can go to another country and simply obtain them.”³²⁷ Similarly, commenters noted that the new regulation did not address concerns over the publication of research related to select agents.³²⁸ On the one hand, restrictions on the publication of scientific research raise serious First Amendment concerns and likely hinder the type of information sharing critical to advances in vaccines and pharmaceuticals.³²⁹ On the other hand, detailed

³²³ See *supra* note 296.

³²⁴ Diana Jean Schemo, *Sept. 11 Strikes At Labs' Doors*, *supra* note 314, at F1. John Parachini, a policy analyst at the RAND Corporation, explained this concern in further detail before the Senate. According to Parachini, “Aum, the Japanese cult group, actually did go to Zaire thinking that they could acquire some Ebola virus. Now, they went in a period where there were not actually outbreaks. But they thought about it. So they did exactly that. And it may be more difficult to actually monitor who is going in and out of hot zones where there are emerging infectious diseases, as opposed to laboratories, where we know where they are – for example in the former Soviet Union – and can focus our attention in improving the security. We should do that. But we should also be aware of this more elusive source that pops up around the world according to its own design, and that it's hard to anticipate where it is.” *Germes, Toxins, and Terror, The New Threat to America: Hearing Before the Subcomm. on Technology, Terrorism, and Government Reform of the Senate Comm. on the Judiciary*, 107th Cong. (2001) (statement of John Parachini, RAND Corporation) (responding to questions posed by Sen. Feinstein).

³²⁵ *Id.* (statement of Dr. Ronald Atlas, President, American Society for Microbiology) (responding to questions posed by Sen. McConnell). John Parachini reiterated this danger in Senate hearings prior to the passage of the PHSBPRA. According to Parachini, “we should be aware that [in] other places, there's not near the accountability as we have in this country, and this problem may be global in scope; indeed, the Ames strain of anthrax has been sent around the world for years. So even if we get our own house in order, which is not an easy task, we've got another sort of circle of challenge before us.” *Id.* (statement of John Parachini, RAND Corporation) (responding to questions posed by Sen. Kyl).

³²⁶ See *id.* (statement of Dr. Ronald Atlas, President, American Society for Microbiology) (responding to questions posed by Sen. McConnell).

³²⁷ *Id.* Atlas also noted that “it does us, I think, little good to know who possesses agents within the United States if we don't similarly know who possesses those agents around the world.” *Id.*

³²⁸ Diana Jean Schemo, *Sept. 11 Strikes At Labs' Doors*, *supra* note 314, at F1. According to one news source, the concept of publication restriction in scientific journals did surface in a Defense Department draft proposal which would have given the government significant control over the publications, speech and travel of scientists who accepted Pentagon research money. *Id.* The proposal, which concerned academics, is purportedly being reconsidered. *Id.*

³²⁹ *Id.*

discussion of agent research could prove useful to would-be terrorists in producing biological weapons.³³⁰ According to one analysis, abstaining from publishing results is “unthinkable” for researchers “bred on the publish-or-perish culture,” particularly when intellectual exchange allows researchers to “do better science, to make better conclusions.”³³¹ Yet as Dr. Gerald Epstein of the Institute for Defense Analysis asserts, “unleashing a highly lethal biological agent [would be] an unparalleled disaster for humanity.”³³² To date, the debate over speech restrictions for scientific research involving biological agents has not been definitively decided.

The comments’ concerns about the tight CDC compliance deadline proved accurate. On November 3, 2003, the CDC amended its interim final rule, primarily to allow for the issuance of provisional registration certificates, as well as provisional access grants, for all entities who submitted information to the Attorney General for a risk assessment prior to the amendment’s date.³³³ Because the CJIS – the FBI division administering the risk assessments – had difficulty processing the thousands of assessment requests received between February 7 and the November 12 regulatory deadline, holding all facilities with outstanding applications in violation of the rule would have shut down a large portion of the research sector.³³⁴ As the CDC noted, “the continued operation of these facilities is vital to the public interest;” thus the purpose of the amendment was to ensure that “both ongoing and new research and educational efforts” important to national defense were not disrupted.³³⁵ According to the amendment, the provisional registration and access certificates would stay in effect until the HHS Secretary either granted or denied an individual or entity’s formal application.³³⁶ The CDC has yet to publish a final rule, and has not disclosed a timeline for doing so.

³³⁰*Id.* The dispute over the publication of scientific research with a potential to aid weapons development emerged with intensity in December 2000, when a team of Australian scientists published the results of a study designed to create a genetically engineered virus to combat the overpopulation of mice. Jon Cohen, *Designer Bugs*, 290 THE ATLANTIC MONTHLY 113-124 (2002), available at <http://www.theatlantic.com/issues/2002/07/cohen-j.htm>. In the course of their study, the scientists had discovered a mechanism that could increase the pathogenicity of a number of human diseases, creating, in effect, “superbugs.” *Id.* For an excellent account of the incident and the issues surrounding academic freedom and dual-use technology, see *id.*

³³¹Diana Jean Schemo, *Sept. 11 Strikes At Labs’ Doors*, *supra* note 314, at F1. Similarly, Ronald Atlas stated that “censoring bits of research erodes the very bedrock of science: the ability of other scientists to replicate results.” Leaving out data, he noted, is “not new to cryptographers and not new to physicists, but it’s new to biologists; biologists have never seen this before.” *Id.*

³³²*Id.*

³³³Possession, Use, and Transfer of Select Agents and Toxins, 68 Fed. Reg. 62245, *supra* note 285.

³³⁴*Id.* at 62245-62246.

³³⁵*Id.* at 62446.

³³⁶*Id.*

V.

In the midst of the CDC's reaction to the changes in its authority brought about by the PHSBPRA, criticism concerning the CDC's regulatory competence – first offered in 1999 congressional hearings in response to the CDC's difficulties in implementing its 1997 rule – reemerged with significant bite. On June 24, 2002, only 10 days after President Bush signed into law the PHSBPRA, the Bush Administration introduced its Homeland Security Bill to the House Select Committee on Homeland Security.³³⁷ Designed to “provide for the security of the American people, territory, and sovereignty” by “uniting under a single department” those federal elements involved in national defense, the Homeland Security Bill proposed transferring several HHS functions, including the CDC Select Agent Program, from DHHS to a newly-created Department of Homeland Security.³³⁸ Under the Bill's provisions, the Secretary of Homeland Security would administer the Select Agent Program “in consultation” with the CDC.³³⁹ While ultimate decisionmaking and administrative authority would rest with the Homeland Security Secretary, the CDC would “continue to make key medical and scientific decisions, such as which biological agents should be included in the select agent list.”³⁴⁰ Such a structure would clearly leave the CDC with little – if any – regulatory authority in the area of biological agent controls. In supporting its recommendation, the Administration echoed earlier arguments against expanding CDC agent oversight to include transfer and possession by asserting that the CDC, at its core, was not – and had never been – a regulatory body but rather a public health agency, and thus was not equipped to manage the burdens and mission conflicts that accompany government oversight.³⁴¹ According to DHHS

³³⁷H.R. 5005, 107th Cong. (2002) (enacted). For a full text of the original bill, see H.R. RPT. 107-609, pt. 1, at 13 (2002).

³³⁸*Id.* at §302(1).

³³⁹*Homeland Security Research and Critical Infrastructure: Hearing Before the House Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 107th Cong. (2002) (statement of Jerome Hauer, Director, Office of Public Health Emergency Preparedness, Department of Health and Human Services).

³⁴⁰*Id.*; see also Kellman, *Regulation of Biological Research in the Terrorism Era*, *supra* note 66, at 166, noting “a certain comfort level has been established both because of long familiarity and because HHS’ mission is to promote health - a mission that is obviously in accord with the work of most biological scientists. Precisely because of this mission, HHS is ill-suited to be the federal agency primarily responsible for preventing terrorist misuse of biological agents. That is primarily a national security or law enforcement function. Its principal motifs entail circumscribing unfettered freedom of action in certain spheres while increasing the government’s access to and control of information - motifs that are substantially at odds with a mission of promoting basic scientific research to the goal of improving human health and welfare.”

³⁴¹*Homeland Security Research and Critical Infrastructure: Hearing Before the House Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 107th Cong. (2002) (statement of Jerome Hauer, Director, Office of Public Health Emergency Preparedness, Department of Health and Human Services).

officials appearing before Congress in support of the Bill, the new Homeland Security Department, endowed with a strong “multi-purpose security and regulatory infrastructure,” would be better suited to prevent unauthorized or miscreant use of select agents.³⁴² The GAO, in its report on the proposed legislation before the House Subcommittee on Oversight and Investigations, agreed with DHHS, noting that the CDC Select Agent Program’s national defense mission was “closely aligned” with homeland security, and that transfer to the new Department would enhance efficiency and accountability.³⁴³ Thus, it was argued that reorganization would “strike the right balance” by utilizing the CDC’s infectious disease expertise while “capitalizing on the strategic and logistical” capacity of the new Department, which would hold law enforcement powers stretching beyond the CDC’s basic verification regime.³⁴⁴ This argument suggested a shift in regulatory emphasis from the promotion of social welfare to the protection of national security.³⁴⁵

Although many in Congress supported the Administration’s position that the CDC did not possess the proper institutional capacity to oversee select agent regulation, a number of robust objections were raised to the Homeland Security Bill’s proposed transfer. First, several members of the House expressed concern that the Bill’s “joint administration” formulation, whereby the Department of Homeland Security managed the Select Agent Program with CDC guidance and input, effectively allowed the new Department to determine CDC research priorities.³⁴⁶ Depending on the staff and resources available to the CDC, directives from the Department related to exercise of the CDC’s “medical and scientific” expertise had the potential to trump other CDC projects, impinging on the agency’s independence.³⁴⁷ Moreover, the Administration’s proposal transferred only the CDC Select Agent Program to the new Department, leaving the USDA’s tracking and registration program for animal agents, as established by the PHSBPRA, untouched. As Representative Tauzin noted, if the rationale for transferring the CDC program was that the Department of Homeland

³⁴² *Id.*

³⁴³ *Id.* (statement of Jan Heinrich, Director, General Accounting Office); *see also* UNITED STATES GENERAL ACCOUNTING OFFICE, HOMELAND SECURITY: NEW DEPARTMENT COULD IMPROVE BIOMEDICAL R&D COORDINATION BUT MAY DISRUPT DUAL-PURPOSE EFFORTS, GAO-02-924T (July 9, 2002).

³⁴⁴ *Homeland Security Research and Critical Infrastructure: Hearing Before the House Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 107th Cong. (2002) (statement of Jerome Hauer, Director, Office of Public Health Emergency Preparedness, Department of Health and Human Services).

³⁴⁵ Kellman, *Regulation of Biological Research in the Terrorism Era*, *supra* note 66, at 160.

³⁴⁶ *Id.* (statement of Rep. Greenwood).

³⁴⁷ *Id.* (statement of Rep. Greenwood) (noting that “given the always finite resources of government,” requests from the DHS to conduct particular research projects would “trump and take priority over CDC’s other projects” and would have the “ability to push some of CDC’s agenda off the table temporarily”); *see also id.* (statement of Rep. Degette) (noting that “practically speaking, if you want to continue ongoing research and then have research of select agents, you’re not going to be able to do both, you are going to have to shift resources away from some ongoing research. And I guess the question many of us are asking is who should be making those decisions – the scientists at CDC and NIH, or somebody who is in this new department who is superceding their decisions?”). DHHS supporters of the transfer noted that the CDC “consistently rearranges priorities based on things that are going on.” *Id.* (statement of Jerome Hauer, Director, Office of Public Health Emergency Preparedness, Department of Health and Human Services) (responding to questions posed by Rep. Greenwood).

Security could provide better coordination with law enforcement, greater investigatory outreach, and stronger logistical tools to prevent misappropriation of dangerous agents, an equally compelling argument could be made to remove the USDA's regulatory oversight, particularly since the USDA's institutional competence was based, as with the CDC, in the scientific identification of threat agents.³⁴⁸ To refuse to transfer both programs also appeared inefficient in light of the program coordination mandated by the PHSBPRA.³⁴⁹ Perhaps the strongest – and most common – complaint was that the CDC possessed a unique institutional capacity to balance the need for regulation with the interests of the scientific community in conducting uninhibited research for benign purposes.³⁵⁰ According to several researchers testifying before Congress, housing the

³⁴⁸ *Id.* (statement of Rep. Tauzin) (questioning Jerome Hauer, Director, Office of Public Health Emergency Preparedness, DHHS, about the absence of a USDA transfer to the DHS). This argument appeared even stronger given that the PHSBPRA mandated that the CDC and USDA coordinate their regulatory programs in an attempt to eventually move to a single registration and tracking system. *Id.* (further pondering, “should both functions be transferred simultaneously, or neither one?”); see also The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594, § 221(c)(2). DHHS officials counterargued that the USDA in fact had a history of broad regulatory action, particularly in its inspection and tracking of animal products, that the CDC lacked. *Homeland Security Research and Critical Infrastructure: Hearing Before the House Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 107th Cong. (2002) (statement of Jerome Hauer, Director, Office of Public Health Emergency Preparedness, Department of Health and Human Services) (responding to questions posed by Rep. Tauzin).

³⁴⁹ *Id.* (statement of Dr. Gail Cassell, Vice President, Eli Lilly and Company). In her testimony, Dr. Cassell offered a strong efficiency rationale: “it is important to coordinate programs related to human, animal, and plant agents because some of the threats for each are the same. . . Subtitle C of the Public Health Security and Bioterrorism Preparedness Act of 2002 mandated coordination of activities of HHS and the Secretary of Agriculture regarding overlap agents- that is, agents that appear on the separate lists prepared by HHS and Agriculture. Coordination among agencies that have regulations for infectious substances is important. Better compliance can be achieved if regulations are clear and coherent, streamlined and integrated, based on real risks, and effectively communicated to individual researchers. Emphasis must be placed on education, guidance and dissemination of information to research investigators, who must clearly understand their role and responsibilities. Institutional Biosafety Committees can be strengthened and there should be qualifications and training for institutional biosafety officers. Laboratory scientists and safety managers in institutions must have input into the rule-making procedures and work to assure that regulations are realistically applied with minimal intrusiveness.” *Id.* Rep. Tauzin supported Cassell's analysis, noting during his introduction of the House Energy and Commerce's substituted text that “if the agricultural select agent program remains at USDA, then the Committee views the transfer of the CDC program as only exacerbating existing coordination problems. We simply do not think it makes sense to transfer half of this program to the new Department, while leaving the other half at another Federal agency.” *Homeland Security Department: Hearing Before the House Select Comm. on Homeland Security*, 107th Cong. (2002) (statement of Rep. Tauzin).

³⁵⁰ *Id.* Dr. Cassell argued that “HHS has the best scientific and institutional knowledge to provide oversight of select registration – and I might add enforcement – and to develop rational enforcement programs.” *Id.* As Cassell further noted, “security for biological facilities is different from security for nuclear and chemical facilities and must take into account the unique aspects of work with biological agents. Inappropriate policy measures and regulations to prevent terrorists from acquiring pathogens could have unintended consequences for research aimed at developing the very countermeasures that could eventually remove agents from the select agent list. There needs to be a careful balancing of public concern about safety and security with the need to conduct legitimate research to protect the public.” *Id.* Ronald Atlas concurred, stating that “the ASM continues to believe that HHS has the scientific and institutional knowledge and expertise related to dangerous biological agents, biosafety, and biosecurity in microbiological and biomedical laboratories and that it is best qualified to achieve the goal of protecting the public health and safety without interfering with research, and clinical and diagnostic laboratory medicine.” *Homeland Security Department: Hearing Before the House Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 107th Cong. (2002) (statement of Dr. Ronald Atlas, President, American Society for Microbiology) (further noting that “the proper administration of the select agent program must balance public concerns for safety with the need to not unduly encumber legitimate research and diagnostic testing. We need an integrated program that adds protection against the misuse the microbial resources”).

Select Agent Program within the Department of Homeland Security could result in “undue tension” with academic and scientific institutions, particularly if “inappropriate policy measures” restricted legitimate agent research.³⁵¹ Finally, critics believed that transferring the CDC oversight function to the Department of Homeland Security would only result in an unnecessary and unwarranted delay in implementing the PHSBPRA’s agent registration scheme.³⁵²

The arguments for vesting regulatory authority in the CDC eventually won the day.³⁵³ The Homeland Security Act, passed November 25, 2002, left the Select Agent Program in control of the CDC, but required the CDC to collaborate with the Department of Homeland Security on the list of regulated agents as well as on laboratory security measures.³⁵⁴ To a certain extent, the CDC benefitted from a strong congressional backlash against transferring any DHHS functions – including agency oversight of public health emergency grants and studies related to biological agent countermeasures – with both a public health and national security component.³⁵⁵ According to several members of Congress, because the staff, resources, and skills necessary for an effective bioterrorism response mirrored those necessary to counter a standard infectious

³⁵¹ *Homeland Security Research and Critical Infrastructure: Hearing Before the House Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 107th Cong. (2002) (statement of Dr. Gail Cassell, Vice President, Eli Lilly and Company); see generally *Homeland Securities Department: Hearing Before the House Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 107th Cong. (2002) (statement of Dr. Ronald Atlas, President, American Society for Microbiology). Dr. Cassell worried about potential DHS control of the CDC regulation: “it is unclear whether the regulations to be put in place within the next 180 days will be changed, taking on more of a criminal approach rather than one based upon scientific knowledge and insights into the biomedical research process utilizing infectious agents. The Administration’s Bill states that interim regulations will be put in place thereby leaving freedom following the transfer of authority to DHS for other regulations to be drafted.” *Homeland Security Research and Critical Infrastructure: Hearing Before the House Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 107th Cong. (2002) (statement of Dr. Gail Cassell, Vice President, Eli Lilly and Company).

³⁵² *Id.* As Dr. Cassell noted, a delay in implementing the CDC regulation would slow down development of the biodefense research agenda by tying laboratories up in the registration process. *Id.*

³⁵³ In fact, the House of Representatives’ version of H.R. 5005 kept DHHS in control of a majority of the federal public health programs dealing with bioterrorism. See Robert Roos, *House Panel Backs Keeping HHS In Charge of Bioterrorism Preparedness*, July 22, 2002, available at <http://www.cidrap.umn.edu/cidrap/content/bt/bioprep/news/dhsleg.html>. In doing so, the House version satisfied “the desire of public health groups not to transfer public health aspects of bioterrorism programs” to DHS, and clearly responded to the concerns of public health groups that a transfer would undermine efforts to strengthen the public health system, as the CDC administers most biodefense programs. *Id.* The House version, which was developed by the House Energy and Commerce Committee, was accepted by the House Select Committee on Homeland Security with few changes. *Id.*

³⁵⁴ Homeland Security Act of 2002, P.L. 107-296, 116 Stat. 2135, § 304 (2002); Robert Roos, *Homeland Security Law Leaves HHS in Control of Bioterrorism Preparedness*, November 22, 2002, available at <http://www.cidrap.umn.edu/cidrap/content/bt/bioprep/news/homelnd.html>. The text of H.R. 5005 was eventually substituted with the text of H.R. 5170, a compromise version. On November 19, 2002, S. AMDT. 4901 substituted text essentially the same as H.R. 5170 into the House bill. See Bill Summary & Status File for H.R. 5005, THOMAS, available at thomas.loc.gov, last visited on April 5, 2004. The House agreed to the Senate amendment on November 22, 2002. *Id.*

³⁵⁵ See, e.g., UNITED STATES GENERAL ACCOUNTING OFFICE, HOMELAND SECURITY: NEW DEPARTMENT COULD IMPROVE BIOMEDICAL R&D COORDINATION BUT MAY DISRUPT DUAL-PURPOSE EFFORTS, *supra* note 343 (stating that the transfer of many DHHS functions to the DHS would “hinder the simultaneous oversight of biodefense and public health” undertaken by the agency); see also Stephen Krupin, *Congress Warned Against Shifting CDC Programs; Ridge, GAO Differ on Bioterror Transfer*, ATLANTA J. & CONST., June 26, 2002, at 3A.

disease outbreak, dual-purpose programs were rightly the province of public health agencies like DHHS and the CDC. In fact, it was even argued that a less stringent regime, situating dual-purpose programs within DHHS but leaving authority in the hands of the new DHS would “create more problems than it would solve,” particularly in terms of ultimate program responsibility.³⁵⁶ The main rationale proffered for keeping the Select Agent Program within the CDC, however, appeared to be that the CDC in fact possessed the appropriate experience balancing concerns for safety with a need to support legitimate research and diagnostic testing.³⁵⁷ Moreover, because the CDC had already begun implementation of the PHSBPRA’s provisions, including the requirement to coordinate regulation with the USDA, a transfer would have served mainly to disrupt and delay the imposition of tighter agent controls. Since the passage of the Homeland Security Act in November 2002, calls for removal of the CDC’s regulatory authority have not publicly resurfaced.

VI.

Several challenges remain as the CDC continues its regulatory oversight of the possession, transfer, and shipment of select agents. First, as previously noted, several agencies in addition to the CDC have authority to regulate the interstate shipment of infectious agents. In fact, while the CDC clearly plays a dominant role in monitoring the location and movement of select agents domestically, its regulations exist alongside a number of other federal rules that also affect agent control.³⁵⁹ In 1990, the CDC first recognized that

³⁵⁶In testimony before the House Select Committee on Homeland Security, Rep. Tauzin voiced the views of the House Committee on Energy and Commerce, noting that “the Committee does not believe it is feasible to separate authority from responsibility, or to separate the officials charged with administering those responsibilities from the personnel required to do so... neither a wholesale transfer of these responsibilities, nor some unusual splitting of responsibilities, is warranted. *Homeland Security Department: Hearing Before the House Select Comm. on Homeland Security*, 107th Cong. (2002) (statement of Rep. Tauzin).

³⁵⁷According to Robert Roos, opposition from public health and research groups prompted Congress to drop the transfer provisions from H.R. 5005 it passed its version of the bill. Robert Roos, *Homeland Security Law Leaves HHS in Control of Bioterrorism Preparedness*, *supra* note 340, available at <http://www.cidrap.umn.edu/cidrap/content/bt/bioprep/news/homelnd.html>. For example, Tara O’Toole, Director of the Johns Hopkins Center for Civilian Biodefense Strategies, argued that “there is a real danger that by sequestering bioterrorism programs in Homeland Security, they will be treated as ‘emergency use only’ functions... reducing the efficiency of preparedness efforts and quite possibly compromising response effectiveness.” Krupin, *supra* note 340, at 3A. O’Toole further stated that “it is a very tall order to ask a single agency to develop national security strategy and create a sophisticated scientific research and development capability over a broad range of disciplines and technology.” *Id.* Ronald Atlas of the American Society for Microbiology further argued that “the CDC has a long history of regulatory oversight concerning bio-safety.”

³⁵⁹See discussion *infra* page 2. No single agency covers all aspects regarding the shipment of infectious substances. Packaging and Handling of Infectious Substances and Select Agents, 64 Fed. Reg. 58022, *supra* note 9, at 58024.

confusion existed among those transporting select agents as to how the varying federal agent requirements related to the CDC rule.³⁶⁰ Yet it wasn't until 1999 that the CDC published a Notice of Proposed Rulemaking designed to harmonize its regulation with shipping and handling requirements imposed by the Department of Transportation, the Occupational Safety and Health Administration, the Environmental Protection Agency, and the U.S. Postal Service, among others.³⁶¹ The Notice of Proposed Rulemaking announced the CDC's intention to revise its guidelines to adhere more closely to other federal regulations and to ensure that shippers and handlers were "aware of and utilized" appropriate packaging when shipping infectious substances.³⁶² In developing its revisions, the CDC consulted with the other federal agencies involved in agent regulation, many of whom are reportedly revising their guidelines as well.³⁶³ The numerous changes proposed by the CDC include the substitution of the Department of Transportation's term "infectious substance" for the CDC's "etiologic agent," the adoption of terminology used by the International Air Transport Association and the Department of Transportation to describe agent containers, including "primary receptacle," "secondary packaging," and "outer packaging," and a revision of the volume/weight limits to comply with Department of Transportation and international guidelines.³⁶⁴ The CDC noted that it intends for its proposed rule to reduce the regulatory burden currently imposed on interstate shippers of agents while improving packaging standards to better protect the public health.³⁶⁵ After publication of the Notice, the CDC invited comments from shippers of infectious materials, persons who transport or handle packages, public health officials, and medical and research laboratories on any of the requirements contained in the proposed rule, particularly those requirements believed by the scientific community to be inconsistent with other regulatory authority.³⁶⁶ Nevertheless, nearly five years later, the CDC has not published a final rule and has not indicated any intention to do so. In order to create a comprehensive regulatory regime and ensure full compliance with CDC rules, the CDC must work to coordinate its requirements with those of other agencies.

³⁶⁰ *Id.* The CDC discovered this confusion during the course of its 1990 proposed rulemaking to update existing agent packaging requirements, *see* Interstate Shipment of Etiologic Agents, 55 Fed. Reg. 7678 (March 2, 1990), when shippers commenting on the proposed rule suggested harmonizing shipping regulations across agencies. *Id.* Commenters noted that confusion stemmed from substantive differences in the requirements of each agency and the use of varying terminology. *Id.*

³⁶¹ *Id.* at 58023-58024.

³⁶² *Id.* at 58024.

³⁶³ *Id.*

³⁶⁴ *Id.* at 58024-58025.

³⁶⁵ *Id.* at 58026.

³⁶⁶ *Id.* at 58024.

A second challenge facing the CDC will be harmonizing its select agent list with similar domestic and international compilations. As previously discussed, in 1999, the CDC developed a “critical agents” list which it used to guide state and local preparedness programs, to determine the formulary for its Strategic National Stockpile, and to ascertain reagents and protocols for the Laboratory Response Network.³⁶⁷ This critical agents list is significantly broader than the select agent list, encompassing less pathogenic – but nonetheless disruptive – agents such as salmonella and shigella.³⁶⁸ The critical agents list also includes a number of highly infectious pathogens, such as Western Equine Encephalitis, not covered by the CDC’s regulation.³⁶⁹ The watchlists of several international regulators closely resemble the CDC’s critical agents lists in depth and breadth. For example, the Australia group, a consortium of 34 countries that imposes limits on the export of materials involved in the development of biological weapons, includes food and waterborne pathogens on its list of restricted material, while NATO’s agent control directorate lists dengue and influenza among restricted agents.³⁷⁰ To date, the CDC has not considered expanding the select agent list to include agents on either its critical agents or international lists, despite the fact that bioterrorism experts have suggested that an attack with a less pathogenic agent represents a more conceivable threat. Clearly, imposing strict regulatory controls on more than the current 40 agents would necessitate a much greater commitment of resources from the CDC and Congress and could represent a severe burden for smaller laboratories, who in turn may discontinue legitimate work on select agents for biodefense and other worthy purposes. One commenter has suggested dividing CDC’s regulatory oversight into two tiers, with highly lethal agents, such as anthrax or plague, subject to more stringent regulation; alternatives to an “all-or-nothing” approach are likely available.³⁷¹ As the CDC continues to conduct biennial reviews of its select agent list, the agency must consider gaps in its monitoring that could undermine the ultimate purpose of its regulatory mission: to ensure that the public health is protected from both accidental and nefarious release of infectious diseases.

Finally, as states begin to institute their own regulatory requirements, federal preemption questions are likely to arise. Although the lines between the federal and state regulatory domain have not always been clear, it

³⁶⁷ See discussion *supra* pp. 32-33.

³⁶⁸ *Id.*

³⁶⁹ Martin Enserink and David Malakoff, *Congress Weighs Select Agent Update*, 294 SCIENCE 1438 (2001).

³⁷⁰ *Id.*

³⁷¹ *Id.*

is undisputed that the regulation of public health has traditionally been a police power of the states, while the regulation of national security was given to the federal government by the Constitution.³⁷² Bioterrorism regulation falls between these two ends of the spectrum, encompassing both public health and national security elements. Thus, the question of who has primary regulatory authority is a murky one. Since the passage of the PHSBPRA in 2002, three states – Arkansas, Maryland, and North Carolina – have passed legislation establishing biological agent registries to monitor the intrastate possession and transfer of agents through state registration procedures.³⁷³ A fourth state – Massachusetts – has similar legislation pending before its State Senate.³⁷⁴ While all four statutes make explicit mention of the CDC regulations and note that their purpose is to enhance cooperation with the CDC in its oversight of select agents, they impose substantially similar requirements as the official CDC rules found at 42 C.F.R. § 73, raising concerns about whether they are preempted by the CDC’s regulation.

Under the doctrine of federal preemption, state law can be preempted by federal statutory law when Congress exercises a granted power.³⁷⁵ Preemption can occur by express provision, by a conflict between federal and state law, or by implication where Congress “so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it.”³⁷⁶ To date, Congress has not preempted state regulation of biological agents by express provision. As to any implication of preemption, the CDC itself has specifically stated that its regulation is not meant to preempt other federal regulations governing the shipment and transfer of biological agents.³⁷⁷ Thus, it is doubtful that one could argue that Congress has implied a different result, as it has, for example, in the area of nuclear power, which involves comprehensive regulation by a single federal agency. Moreover, Congress has consistently encouraged states to take proactive steps to respond to the threat of bioterrorism. To give just one example, the CDC and representatives of several states are in the process of implementing the Model State Emergency Health Powers

³⁷²Victoria Sutton, *Bioterrorism Preparation and Response Legislation: The Struggle to Protect States’ Sovereignty While Preserving National Security*, 6 THE GEO. PUB. POL’Y REV. 93 (Spring 2001), available at <http://www.ttu.edu/biodefense/publications.php>.

³⁷³A.C.A. § 20-36-101 (2003); MD. CODE ANN. § 17-602 (2003); N.C. GEN. STAT. § 130A-479 (2004).

³⁷⁴MA S.B. 511 (2003).

³⁷⁵Sutton, *supra* note 310, at 2. Congress’ “granted power” is the power to regulate interstate commerce under the Commerce Clause.

³⁷⁶Id. at 14 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947), *Maryland v. Louisiana*, 451 U.S. 725 (1981), and *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519 (1978), respectively).

³⁷⁷Additional Requirements for Facilities Transferring or Receiving Select Agents, 61 Fed. Reg. 55190, *supra* note 71, at 55192. In *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947), the Supreme Court held that field preemption requires a clear showing that Congress meant to occupy the field. This showing could be discerned according to either (1) the pervasiveness of the regulation, which would support an inference that Congress left no room for state law, or (2) recognition of a federal interest so dominant that the federal system would have been assumed to preclude state law.

Act, designed to update state quarantine laws to provide greater authority in the event of a bioterrorist strike.³⁷⁸ Current trends in federalism also suggest a shift towards greater state power.³⁷⁹ Yet an issue of conflict preemption clearly may remain. On the one hand, it can be argued that the CDC regulation only creates a floor for agent control. If CDC regulation is no more than a floor, states are free to impose their own registration requirements as necessary. This is a compelling argument given that public health regulation vests first in the states, and that dual federal-state regulation may ensure fewer gaps in oversight. On the other hand, many laboratories have already experienced significant implementation difficulties related to the cost of complying with the CDC regulation, raising worries that additional state requirements may lower the effectiveness of the CDC rule.³⁸⁰ Moreover, the Supreme Court has found conflict preemption when the federal government has created a “complete scheme of regulation,” a context arguably present in 42 C.F.R. § 73.³⁸¹ This issue has not yet been brought before a federal court, and clearly merits greater discussion.

In summary, the CDC’s regulation of biological agents can be characterized as an expansion of the agency’s role from simple monitor of physical security to overseer of a comprehensive national regulatory scheme. The AEDPA and PHSBPRA instituted important augmentations of the CDC’s power to prevent unauthorized agent access and rightly reflected the nation’s changing national security interests. However, until other countries adopt similar legislation or impose more stringent restraints on the movement of agent cultures, successful CDC oversight will depend in large part on the integrity of laboratory workers and on the continued commitment of the academic and scientific community to full compliance.

³⁷⁸ See <http://www.publichealthlaw.net>.

³⁷⁹ Sutton, *supra* note 310, at 14.

³⁸⁰ See *Crosby v. National Foreign Trade Council*, 550 U.S. 363 (2000) (holding that Congress’ passage of a federal law imposing mandatory sanctions on a foreign country preempted a more stringent state law because the state law presented “an obstacle to the accomplishment of Congress’s full objectives”).

³⁸¹ See *Hines v. Davidowitz*, 312 U.S. 52 (1941) (stating that “where the federal government . . . has enacted a complete scheme of regulation . . . state cannot, inconsistently with the purpose of Congress, conflict or interfere with, curtail or complement, the federal law, or enforce additional or auxiliary regulations”).

Appendix 1³⁸²
DHHS Select and Overlaps Agents

HHS NON-OVERLAP SELECT AGENTS AND TOXINS

- Crimean-Congo haemorrhagic fever virus
- Coccidioides posadasii
- Ebola viruses
- Cercopithecine herpesvirus 1 (Herpes B virus)
- Lassa fever virus
- Marburg virus
- Monkeypox virus
- Rickettsia prowazekii
- Rickettsia rickettsii
- South American haemorrhagic fever viruses
- o
Junin

³⁸²Available at <http://www.cdc.gov/od/sap>.

- o
 - Machupo
- o Sabia
- o
 - Flexal
- o
 - Guanarito
- - Tick-borne encephalitis complex (flavi) viruses
 - o Central European tick-borne encephalitis
 - o Far Eastern tick-borne encephalitis
 - o Russian spring and summer encephalitis
 - o Kyasanur forest disease
 - o
 - Omsk hemorrhagic fever
- - Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)

- *Yersinia pestis*
- Abrin
- Conotoxins
- Diacetoxyscirpenol
- Ricin
- Saxitoxin
- Shiga-like ribosome inactivating proteins
- Tetrodotoxin

HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS/ SELECT AGENTS (OVERLAP AGENTS)

- Bacillus anthracis
- Brucella abortus
- Brucella melitensis
- Brucella suis
- Burkholderia mallei (formerly Pseudomonas mallei)

- Burkholderia pseudomallei (formerly Pseudomonas pseudomallei)
- Botulinum neurotoxin producing species of Clostridium
- Coccidioides immitis
- Coxiella burnetii
- Eastern equine encephalitis virus
- Hendra virus
- Francisella tularensis
- Nipah Virus
- Rift Valley fever virus
- Venezuelan equine encephalitis virus
- Botulinum neurotoxin
- Clostridium perfringens epsilon toxin
- Shigatoxin

- Staphylococcal enterotoxin.

- T-2 toxin

USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS (NON-OVERLAP)

- Akabane virus
- African swine fever virus
- African horse sickness virus
- Avian influenza virus (highly pathogenic)
- Blue tongue virus (Exotic)
- Bovine spongiform encephalopathy agent
- Camel pox virus
- Classical swine fever virus
- Cowdria ruminantium (Heartwater) Foot and mouth disease virus

- Goat pox virus
- Lumpy skin disease virus
- Japanese encephalitis virus
- Malignant catarrhal fever virus (Exotic)
- Menangle virus
- Mycoplasma capricolum/
- M.F38/M. mycoides capri
- Mycoplasma mycoides mycoides
- Newcastle disease virus (VVND)
- Peste Des Petits Ruminants virus
- Rinderpest virus
- Sheep pox virus

- Swine vesicular disease virus

-

Vesicular stomatitis virus (Exotic)

LISTED PLANT PATHOGENS

-

Liberobacter africanus

-

Liberobacter asiaticus

- *Peronosclerospora philippinensis*

-

Phakopsora pachyrhizi

-

Plum Pox Potyvirus

-

Ralstonia solanacearum race 3, biovar 2

-

Schlerophthora rayssiae var *zeae*

- *Synchytrium endobioticum*

-

Xanthomonas oryzae

-

Xylella fastidiosa (citrus variegated chlorosis strain)

Appendix 2³⁸³

CDC Timeline for Implementation of its Interim Final Rule

EFFECTIVE DATES

Date	Applicants Possessing Agents on or Before 2/7/03	Applicants Not Possessing on or Before 2/7/03
Dec. 13, 2002	Publication of interim Final Rule	Publication of interim Final Rule
Feb. 7, 2003	Safety; Emergency Response; Training; Records; Notification of Theft, Loss or Release	Safety; Emergency Response; Training; Records; Notification of Theft, Loss or Release; DOJ review for entity, RO, and individuals; Transfer Section Effective

³⁸³ Available at <http://www.cdc.gov/od/sap/cdc-05a.htm>.

Mar. 12, 2003	Certifies that ap- pli- ca- tions for DOJ re- view for en- tity and RO Sub- mit- ted; Trans- fer Sec- tion Ef- fec- tive	
April 12, 2003	Application for DOJ review for Individuals submitted; Entity and RO DOJ review completed	

June 12, 2003	Individual DOJ Re- view Com- plete; De- vel- op- ment of Se- cu- rity Plan	Development of Se- cu- rity Plan
Sept. 12, 2003	Security Plan Implemented; Training (Security Provisions)	Security Plan Implemented; Training (Security Provisions)
Nov. 12, 2003	Registration Section Effective; Entity must be in full compliance with 42 CFR 73.0	Registration Section Effective; Entity must be in full compliance with 42 CFR 73.0